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For: ARTICULATING SUTURING DEVICE AND METHOD

Enclosed are:

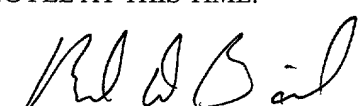
- ☒ [ X ] Title Page;
- ☒ [ X ] Eighteen (18) pages of specification;
- ☒ [ X ] Eight (8) pages of claims;
- ☒ [ X ] One (1) page of Abstract;
- ☒ [ X ] Fourteen (14) sheets of informal drawings;
- ☒ [ X ] An unsigned Declaration.

In view of the Unsigned Declaration as filed with this application and pursuant to 37 CFR §1.53(f), Applicant requests deferral of the filing fee until submission of the Missing Parts of Application.

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**PATENT APPLICATION**  
**ARTICULATING SUTURING DEVICE AND METHOD**

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## ARTICULATING SUTURING DEVICE AND METHOD

### 5 BACKGROUND OF THE INVENTION

#### 1. Field of the Invention

The present invention relates generally to apparatus and methods for the suturing of body lumens. More particularly, the present invention relates to techniques for percutaneous closure of arterial and venous puncture sites, which are usually accessed  
10 through a tissue tract.

A number of diagnostic and interventional vascular procedures are now performed transluminally. A catheter is introduced to the vascular system at a convenient access location and guided through the vascular system to a target location using established techniques. Such procedures require vascular access, which is usually  
15 established during the well-known Seldinger technique, as described, for example, in William Grossman's "Cardiac Catheterization and Angioplasty," 3<sup>rd</sup> Ed., Lea and Febiger, Philadelphia, 1986, incorporated herein by reference. Vascular access is generally provided through an introducer sheath, which is positioned to extend from outside the patient body into the vascular lumen.

20 When vascular access is no longer required, the introducer sheath is removed and bleeding at the puncture site stopped. One common approach for providing hemostasis (the cessation of bleeding) is to apply external force near and upstream from the puncture site, typically by manual or "digital" compression. This approach suffers from a number of disadvantages. It is time consuming, frequently requiring one-half hour  
25 or more of compression before hemostasis is assured. Additionally, such compression techniques rely on clot formation, which can be delayed until anticoagulants used in vascular therapy procedures (such as for heart attacks, stent deployment, non-optical PTCA results, and the like) wear off. This can take two to four hours, thereby increasing the time required before completion of the compression technique. The compression  
30 procedure is further uncomfortable for the patient and frequently requires analgesics to be

tolerable. Moreover, the application of excessive pressure can at times totally occlude the underlying blood vessel, resulting in ischemia and/or thrombosis. Following manual compression, the patient typically remains recumbent from four to as much as twelve hours or more under close observation so as to assure continued hemostasis. During this time renewed bleeding may occur, resulting in blood loss through the tract, hematoma and/or pseudo-aneurysm formation, as well as arteriovenous fistula formation. These complications may require blood transfusion and/or surgical intervention.

The incidence of complications from compression induced hemostasis increases when the size of the introducer sheath grows larger, and/or when the patient is anti-coagulated. It is clear that the compression technique for arterial closure can be risky, and is expensive and onerous to the patient. Although the risk of complications can be reduced by using highly trained individuals, dedicating such personnel to this task is both expensive and inefficient. Nonetheless, as the number and efficacy of translumenally performed diagnostic and interventional vascular procedures increases, the number of patients requiring effective hemostasis for a vascular puncture continues to increase.

To overcome the problems associated with manual compression, the use of bioabsorbable fasteners or sealing bodies to stop bleeding has previously been proposed. Generally, these approaches rely on the placement of a thrombogenic and bioabsorbable material, such as collagen, at the superficial arterial wall over the puncture site. While potentially effective, this approach suffers from a number of problems. It can be difficult to properly locate the interface of the overlying tissue and the adventitial surface of the blood vessel. Locating the fastener too far from that interface can result in failure to provide hemostasis, and subsequent hematoma and/or pseudo-aneurysm formation. Conversely, if the sealing body intrudes into the artificial lumen, intravascular clots and/or collagen pieces with thrombus attached can form and embolize downstream, causing vascular occlusion. Also, thrombus formation on the surface of a sealing body protruding into the lumen can cause a stenosis, which can obstruct normal blood flow. Other possible complications include infection, as well as adverse reaction to the collagen or other implant.

A more effective approach for vascular closure has been proposed in U.S. Patent Nos. 5,417,699, 5,613,974; and PCT published Patent Application No. PCT/US96/10271 filed on June 12, 1996, the full disclosures of which are

incorporated herein by reference. A suture applying device is introduced through the tissue tract with a distal end of the device extending through the vascular puncture. One or more needles in the device are then used to draw suture through the blood vessel wall on opposite sides of the puncture, and the suture is secured directly over the adventitial surface of the blood vessel wall to provide highly reliable closure.

While a significant improvement over the use of manual pressure, clamps, and collagen plugs, certain design criteria have been found to be important to successful suturing to achieve vascular closure. For example, it is highly beneficial to properly direct the needles through the blood vessel wall at a significant distance from the puncture so that the suture is well anchored in the tissue and can provide tight closure. It is also highly beneficial to insure that the needle deployment takes place when the device is properly positioned relative to the vessel wall. The ease of deployment and efficacy of the procedure can further be enhanced by reducing the cross-section of that portion of the device which is inserted into the tissue tract and/or the vessel itself, which may also allow closure of the vessel in a relatively short amount of time without imposing excessive injury to the tissue tract or vessel.

For the above reasons, it would be desirable to provide improved devices, systems, and methods for suturing vascular punctures. It would be particularly beneficial if these improved devices provided some or all of the benefits while overcoming one or more of the disadvantages discussed above.

## 2. Description of the Background Art

U.S. Patent Nos. 5,700,273, 5,836,956, and 5,846,253 describe a wound closure apparatus and method in which needles are threaded with suture inside a blood vessel. U.S. Patent No. 5,496,332 describes a wound closure apparatus and method for its use, while U.S. Patent No. 5,364,408 describes an endoscopic suture system.

U.S. Patent No. 5,374,275 describes a surgical suturing device and method of use, while U.S. Patent No. 5,417,699 describes a device and method for the percutaneous suturing of a vascular puncture site. An instrument for closing trocar puncture wounds is described in U.S. Patent No. 5,470,338, and a related device is described in U.S. Patent No. 5,527,321. U.S. Patent No. 5,507,757 also describes a method of closing puncture wounds.

## SUMMARY OF THE INVENTION

The present invention provides improved devices, systems, and methods for suturing of body lumens. The device often allows the suturing of vascular puncture sites located at the distal end of a percutaneous tissue tract with greater ease, in less time, and with less patient trauma than known systems. These improvements are generally provided through the use of shafts having smaller cross-sections than prior suturing systems. In the exemplary embodiment, an elongate articulated foot near a distal end of a shaft is inserted through the penetration and actuated so that the foot extends along the luminal axis. The foot carries suture attachment cuffs, and can be drawn proximally up against the endothelial surface of the blood vessel. Needles are advanced from the shaft, through the vessel wall beyond the penetration, and into engagement with the needle cuffs. The cross-section of the shaft within the tissue tract can be minimized by laterally deflecting the needles before they leave the shaft, while tapered depressions within the foot can help guide the advancing needles into engagement with the cuffs. The cuffs lockingly engage the needles so that the cuffs can be withdrawn proximally along the needle paths through the tissue tract so as to form a loop of suture across the puncture without having to thread the needles directly with the suture inside the blood vessel. The suture loop may be drawn distally from the shaft, proximally from within the blood vessel, or laterally down one of the needle paths, across the puncture, and out the opposing path. Regardless, the articulating foot may be realigned with the shaft and withdrawn proximally through the tissue tract in a small profile configuration. The use of an articulatable foot in combination with lateral deflection of the needles can avoid dilation of the tissue tract, as was often necessary using known puncture closure systems.

In a first aspect, the invention provides a method for suturing a puncture through a vessel wall of a blood vessel. The puncture is disposed within a tissue tract of a patient body, and the method comprises attaching a flexible filament to a first fitting. The first fitting is inserted through the tissue tract and positioned adjacent the vessel wall, and a needle path is formed by advancing a first needle through the vessel wall. The needle is coupled with the first fitting, and the first needle, the first fitting, and at least a portion of the filament are withdrawn through the vessel wall along the needle path.

First and second fittings will often be coupled to the flexible filament, and will generally be positioned so that the puncture is disposed therebetween. The flexible filament will often comprise a suture extending between the first and second fittings, with

each fitting being drawn proximally by an associated needle so as to form the suture loop. Alternatively, at least one of the needles may include a detachable tip and may advance a suture distally along the needle path as the needle penetrates through the vessel wall. The flexible filament can again couple the first and second fittings, here allowing both fittings  
 5 to be withdrawn along a single needle path so that the suture advances down along the first needle path, laterally across the puncture, and then out the other needle path.

Positioning of the fittings is generally effected by articulating an elongate foot within the blood vessel so that the foot extends along the vessel axis. A confirmation lumen may extend along a shaft supporting the foot to ensure that the foot is positioned  
 10 within the vessel prior to articulation. Once the foot is properly articulated, it can be withdrawn to firmly engage the endothelial layer of the vessel. The foot will preferably include tapering depressions which direct the advancing needle toward the fitting, and the suture or other flexible filament adjacent the fittings will often be releasably restrained within a narrow slot extending from the depression. The suture or other flexible filament  
 15 and its associated slot will preferably be arranged to avoid entanglement of the advancing needle in the suture, and to ensure that the fitting and suture can be withdrawn proximally as the needle is retracted. An atraumatic, flexible monorail guidebody may extend from the shaft and/or the articulatable foot to facilitate alignment of the foot with the vessel, and also to help provide hemostasis while the knot is tied. A wide variety of foot  
 20 articulation mechanisms may be provided, with deployment preferably being effected when the foot is disposed entirely within the vessel and using an actuator and foot motion that avoid dilation of the puncture.

In another aspect, the invention provides a method for suturing an opening in a tissue. The method comprises inserting a distal end of a probe through the opening,  
 25 the probe defining a probe axis. An elongated foot of the probe is articulated so that first and second ends of the foot extend laterally with the opening aligned therebetween. A first needle path is formed from the probe, through the tissue, and to the first end of the foot. A second needle path is formed from the probe, through the tissue, and to the second end of the foot. Suture is advanced along the first and second needle paths to  
 30 position a suture loop across the opening.

In another aspect, the invention provides a method for suturing a blood vessel. The vessel has a vessel wall, and the method comprises advancing a shaft toward the vessel wall. The shaft has an axis and a plurality of needle guides. A foot is deployed

adjacent the vessel wall so that the foot extends laterally from the shaft. A plurality of needles are advanced from the needle guides of the shaft to the foot to form needle paths through the vessel wall. The needle guides deflect the needles laterally so that a needle path width between the needles is greater than a cross-sectional dimension of the shaft.

- 5 Suture is advanced along the needle paths to position at least one suture loop across the puncture.

In yet another method of the present invention, a blood vessel is sutured through a tissue tract of a patient body. The vessel has a vessel wall, and the method comprises inserting a distal end of a probe through the puncture and into the blood vessel.

- 10 A first end of the suture is advanced from the probe within the tissue tract, through the vessel wall, and into the vessel. The first end of the suture is withdrawn from the vessel through the vessel wall, and through a bight of the suture to form a loop of suture across the puncture. The first end of the suture and a second end of the suture adjacent the bight are tensioned to detach the bight from the probe and form a knot affixing the loop of
- 15 suture across the puncture. Advantageously, the bight of suture may be pre-tied before the probe is inserted into the tissue tract, the bight optionally being releasably attached to the probe.

In a device aspect, the invention provides a system for suturing a blood vessel. The vessel has a vessel wall, and the system comprises a needle having a

20 proximal end and a distal end suitable for forming a needle path through the vessel wall. The needle has a recessed engagement surface adjacent the distal end. The system further comprises a flexible filament and a fitting attached to the filament. The fitting has an opening and a tab extending into the opening, the tab securingly engaging the engagement surface when the needle advances through the vessel wall and into the opening, so that the

25 fitting and at least a portion of the filament can be withdrawn proximally along the needle path by the needle.

- In a further device aspect, the invention provides a system for suturing a puncture of a blood vessel within a tissue tract. The vessel has a vessel wall and defines an axis, and the system comprises a shaft having a proximal handle and a distal end
- 30 suitable for insertion along the tissue tract and into the vessel through the puncture. A foot is mounted near the distal end of the shaft. The foot has plurality of needle receptacles extendable laterally from the shaft. A flexible filament extends between the



receptacles of the foot. A plurality of needles are advanceable distally and laterally from the shaft, through the vessel wall outside the puncture, and to the receptacles of the foot.

In yet another device aspect, the invention provides a system for suturing a puncture of a blood vessel within a tissue tract. The vessel has a vessel wall, and the system comprises a shaft having a proximal handle and a distal end suitable for insertion along the tissue tract and into the vessel through the puncture. A foot is mounted near the distal end of the shaft. The foot has a first needle receptacle and is articulatable from a small profile configuration to a large profile configuration by actuation of the handle. A first fitting is removably mounted adjacent the first needle receptacle. A filament is coupled to the first fitting. A first needle is advanceable from the shaft to the first needle receptacle on the articulated foot. The first fitting securely engages the first needle so that the secured first fitting and at least a portion of the filament can be drawn through the vessel wall by the first needle.

In a still further device aspect, the invention provides a probe for suturing an opening in a tissue. The probe comprises a shaft having a proximal end and a distal end and defining an axis therebetween. The shaft has a size and configuration suitable for insertion through the opening in the tissue. An elongate foot is movably mounted to the shaft. An actuator extends along the shaft distally to the foot. Movement of the actuator slides the foot axially and pivots the foot from a low profile configuration to a deployed configuration extending laterally from the shaft. A suture is supported by the foot, and a needle is advanceable from the shaft, through the tissue, and to the deployed foot.

#### BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a perspective of a percutaneous blood vessel closure device according the principles of the present invention.

Fig. 2 illustrates the vessel closure device of Fig. 1 in which an elongate foot is shown in a deployed position.

Figs. 2A-C illustrate actuation of a foot and advancement of needles from a shaft to the articulated foot in a probe similar to the probe of Fig. 1.

Fig. 3A is a detailed view showing the foot of the vessel closure device of Fig. 1 in a parked position prior to deployment.

Fig. 3B is a detailed view showing the foot of the vessel closure device of Fig. 1 in a deployed position.

Figs. 4 and 4A are perspective views illustrating a suture attachment cuff and an associated barbed needle for use in the vessel closure device of Fig. 1.

Fig. 5 is a cross-sectional view showing the barbed needles securingly engaging the suture cuffs of the deployed foot.

5 Figs. 6A-C illustrate one embodiment of a deployable foot, in which the foot slides and pivots when drawn proximally by a tension member.

Fig. 7 illustrates the suture cuff positioned within a needle receptacle, and also shows how the suture is releasably secured within a slot extending radially from the needle receptacle.

10 Figs. 8A-C illustrate an alternative foot articulation mechanism in which lateral slots on the foot receive pins from the shaft to allow the foot to pivot and slide axially.

Figs. 9A and B illustrate a still further alternative foot actuation mechanism in which the foot slides axially within a slot.

15 Figs 9C and D illustrate a further foot actuation mechanism in which relative movement between the sides of a two-part shaft actuates the foot.

Figs. 10A-D illustrate alternative structures and techniques for avoiding entanglement of the needle with the suture.

20 Figs. 11A-E illustrate an alternative closure system and method for its use in which a first needle advances the suture to the foot, while a second needle engages and withdraws both the first and second suture cuffs, a flexible filament connecting the suture cuffs, and at least a portion of the suture from within the blood vessel so as to complete a pre-tied knot.

25 Figs. 12A and B illustrate an alternative probe having two pairs of needles and a foot with four needle receptacles so as to form two loops of suture across a puncture of a blood vessel.

Figs 13A-G illustrate a method for use of a suture system so as to effect hemostasis of a blood vessel puncture through a tissue tract.

## 30 DESCRIPTION OF THE SPECIFIC EMBODIMENTS

Referring now to Fig. 1, a vessel closure device 10 generally has a shaft 12 having a proximal end 14 and a distal end 16. A proximal housing 18 supports a needle

actuation handle 20. A flexible, atraumatic monorail guidebody 22 extends distally of distal end 16 of shaft 12.

As can be seen with reference to Fig. 2, a foot 24 is articulatably mounted near the distal end of shaft 12. Foot 24 moves between a low profile configuration, in which the foot is substantially aligned along an axis of shaft 12 (as illustrated in Fig. 1), to a deployed position, in which the foot extends laterally from the shaft, upon actuation of a foot actuation handle 26 disposed on proximal housing 18.

Figs 2A through C illustrate the structure and actuation of foot 24 of a preferred probe 10' having a modified proximal housing, and also show how needles 38 can be advanced distally from shaft 12 to the foot by depressing needle actuation handle 20.

Actuation of foot 24 is illustrated more clearly in Fig. 3A and B. In the parked position illustrated in Fig. 3A, foot 24 extends substantially along axis 28 of shaft 12. Note that the axis of the shaft need not be straight, as the shaft may curve somewhat, particularly adjacent the foot. In the exemplary embodiment, foot 24 is substantially disposed within a foot receptacle 30 of shaft 12 so as to minimize the cross-section of the device adjacent the foot prior to deployment. Advantageously, prior to deployment of the foot, device 10 can have a cross-section adjacent foot 24 of about 7 Fr or less, ideally having a cross-section of about 6 Fr or less for the entire device distally of the proximal end 14 of shaft 12.

Actuation of foot handle 26 slides a foot actuation wire 32 proximally, pulling foot 24 from a parked position to the deployed position illustrated in Fig. 3B. Once deployed, a first end 24a and a second end 24b of foot 24 extend laterally from the shaft. Suture 34 here comprises a continuous filament with ends disposed in needle receptacles adjacent each end of the foot. An intermediate portion of suture 34 may extend proximally along a suture lumen of shaft 12 to and/or beyond proximal housing 18. Alternatively, in preferred probe 10', the length of suture between the ends may extend distally within flexible guidebody 22, preferably in a dedicated lumen (separate from the monorail guidewire lumen). In still further alternatives described below, a short length of suture or some other flexible filament may extend substantially directly between the needle receptacles.

Shaft 12 also includes a foot position verification lumen that extends distally from a position verification port 36 to a position indicator at housing 18. When

the foot is properly positioned within the blood vessel, blood pressure will cause blood to flow proximally through the indicator lumen to the indicator. The indicator may optionally comprise a blood exit port, a clear receptacle in which blood is visible, or the like. In the exemplary embodiment, the indicator of handle 18 comprises a length of clear tubing extending from housing 18 (not shown) in which the blood is clearly visible. It should be understood that a wide variety of alternative position verifications sensors might be used, including electrical pressure sensors, electrolytic fluid detectors, or the like.

The structures used in positioning a loop of suture across the puncture can be understood with reference to Figs. 4, 4A, and 5. In general terms, needles 38 extend from shaft 12 into secured engagement with fittings 40 attached to sutures 34. More specifically, needles 38 include a barbed end 42 defining a recessed engagement surface 44. Fittings 40 are roughly cylindrical structures having an axial channel 46 which receives barbed end 42 of needle 38 therein. A first slot is cut in fitting 44 so as to define at least one tab 48. Tabs 48 can be resiliently biased inward into channel 46. As needle 38 advances into fitting 40, barbed end 42 resiliently displaces tab 48 clear of channel 46 so as to allow the barbed end to pass axially into the fitting. Once barbed end 42 is disposed axially beyond tab 48, the tab resiliently flexes back into the channel, capturing needle 38 by engagement between the tab and recessed surface 44. As each tab can hold the fitting in place on the needle, the use of more than one tab increases the reliability of the system. Ideally, three tabs are provided, as illustrated in Fig. 4A.

To facilitate attachment of fitting 40 to suture 34, a second slot cut in the tubular fitting structure defines a suture attachment collar 50. Optionally, collar 50 may be crimped about suture 34 to mechanically affix the suture to fitting 40. In addition and/or instead of mechanical crimping, suture 34 may be bonded to fitting 40 using an adhesive, heat, fasteners, knots, or the like.

Fitting 40 is quite small in size, and is generally configured to facilitate withdrawing the fitting (and the attached suture) along with needle 38 axially through the vessel wall along the needle path. Needle 38 will generally have a cross-sectional width of between about 0.010 inches and 0.020 inches. Barb 42 will extend laterally so as to define an engagement surface 44 having a protruding length of between about 0.002 inches and 0.005 inches. Fitting 40 will preferably have a cross-sectional size roughly corresponding to or only slightly larger than needle 38. Fitting 40 will typically have an

outer lateral width of between about 0.014 inches and 0.025 inches, and an axial length of between about 0.035 inches and 0.050 inches. Channel 46 will be sized to receive at least a portion of needle 38, and will generally have a width of between about 0.010 inches and 0.020 inches. Suture 34 will preferably extend axially opposite the open end of channel 46 so as to minimize drag when the suture is drawn proximally along the needle path. In the exemplary embodiment, needle 38 has a diameter of about 0.020 inches, while the fitting comprises a tube having an outer diameter of about 0.020 inches, an inner diameter of about 0.016 inches, and an overall length of about 0.047 inches. The fitting will typically comprise a resilient material, preferably comprising a metal, and in the exemplary embodiment, comprising stainless steel.

Needles 38 typically have a length of between about 5.0 inches and 6.0 inches, and will preferably be sufficiently stiff to be advanced in compression through the vessel wall (and adjacent tissues) for up to 0.5 inches when supported in cantilever. Nonetheless, the needles will ideally be flexible enough to be laterally deflected within shaft 12, as can be understood with reference to Fig. 5. Needles 38 generally comprise a high strength metal, ideally comprising stainless steel. Fittings 40 will also preferably comprise a flexible material to allow tab 48 to flex out of the way of barbed end 42, and to resiliently rebound and engage recessed surface 44. In the exemplary embodiment, barbed end 42 has a diameter of about 0.015 inches, with the diameter of the needle decreasing to about 0.008 inches proximally of the barb so as to define the recessed engagement surface.

As was generally described above, foot 24 includes needle receptacles adjacent the ends of the foot. A fitting 40 (with an associated end of suture 34) is disposed within each needle receptacle, and a surface of the receptacle tapers proximally and outwardly so as to guide the advancing needles 38 into engagement with fittings 40 when foot 24 is in the deployed position. As fittings 40 (and associated portions of suture 34) are releasably supported in the foot, needles 38 can be withdrawn proximally so as to draw the fittings and suture ends from the foot proximally into (and optionally through) shaft 12. The needle receptacles of the exemplary embodiment taper outward at an angle between 20 and 35 degrees from the centerline of fitting 40, and the fitting is held in a recess having a diameter of about 0.0230 inches and a length of about 0.042 inches. A lateral opening or window through the side of foot to the fitting recess may be provided to

facilitate needle and/or cuff positioning during assembly of the probe, and a protruding collar near the proximal end of the fitting recess may help keep the fitting in position.

Fig. 5 also illustrates the lateral deflection of needles 38 by needle guides 54 of shaft 12. This lateral deflection of the needles allows the use of a small diameter shaft, while still encompassing sufficient tissue within the suture loop on opposite sides of the puncture so as to effect hemostasis when the suture looped is tightened and secured. In the exemplary embodiment, shaft 12 comprises an outer casing of a biocompatible material such as stainless steel, carbon fiber, nylon, another suitable polymer, or the like. Needle guides 54 may be defined at least in part as lumens formed within the casing of a polymeric material such as nylon or the like. In some embodiments, shaft 12 may comprise a carbon fiber filled nylon, or carbon fiber filled with an alternative material.

One example of a suitable structure and articulation motion for foot 24 is illustrated in Figs. 6A and B. Foot actuation wire 32 (see Fig. 3A) rides in a lumen of shaft 12, and draws foot 24 from a parked position (shown in Fig. 6A) to a deployed position (shown in Fig. 6B) through a combination of sliding and pivoting of the foot. The foot remains supported throughout its range of motion by arms disposed laterally on either side of the foot, the arms defining (at least in part) foot receptacle 30. Once foot 24 is deployed, needle receptacles 52 and/or the fittings disposed therein will preferably define a lateral suturing width 56 in a range from about 0.260 inches to about 0.300 inches. Foot 24 may be machined or cast from a polymer or metal, but will preferably comprise a polymer such as carbon fiber filled nylon. In some cases, foot 24 may be molded as two separate halves which can subsequently be affixed together. Needles 38 advance from the fixed needle guides 54, and are laterally directed into fittings 40 by receptacles 52, as illustrated in Fig 6C. In general, a shape memory alloy such as Nitinol™ in its superelastic regime provides a particularly advantageous actuator wire for manipulating foot 24.

Referring now to Fig. 7, fittings 40 and suture 34 will be withdrawn proximally by the needles from needle receptacles 52. To releasably support fittings 40 and suture 34 and avoid entanglement of the suture in the needles, suture 34 is fittingly received within a slot 58 which extends laterally from needle receptacles 52. As the needles pull the fitting axially from needle receptacles 52, suture 34 is pulled from slot 58 and free from foot 24. Bending of the suture proximally within the suture slot can also

locally increase the suture width, so that the interaction between the bent suture and the slot can help hold the fitting in the recess.

A wide variety of foot actuation mechanisms might be used within the scope of the present invention. A first alternative foot actuation arrangement is illustrated in Figs. 8A-C. In this embodiment, a shaft 12*i* has pins 60 which ride in associated slots 62 of a foot 24*i*. Proximal motion of an actuation wire causes foot 24*i* to move axially and rotationally, with pins 60 sliding along slot 62, and the foot pivoting about the pins. In this embodiment, guidebody 22 extends directly from the foot, as illustrated in Fig. 8C.

A still further alternative foot actuation mechanism is illustrated in Figs. 9A and B. In this embodiment, slidable foot 24*ii* is slidably received within a receptacle 30 of shaft 12*ii*. Sliding of the foot 24*ii* from the parked position of Fig. 9A to the deployed position of Fig. 9B places the needle receptacles 52 in the paths of needles from the shaft 12*ii* without pivoting of the foot. Guidebody 22 (see Fig. 1) will extend here from a distal end of shaft 12*ii* at a fixed angle from the shaft. Optionally, insertion through the tissue tract may be facilitated by including an additional bend in the shaft axis adjacent the guidebody on many embodiments.

Yet another foot actuation mechanism can be understood with reference to Figs. 9C and D. Shaft 12*iii* is formed in two parts, which slide axially relative to each other when foot actuation lever 26*iii* moves, using an offset crank arrangement. A similar offset crank supports foot 24*iii*, so that the sliding shaft parts cause the foot to pivot as shown.

A variety of features may be included in the articulatable foot, the needle receptacle, and/or the needle to avoid tangling of the needle in the suture as the needle is directed to the fitting. As illustrated in Fig. 10A, a moveable flap 64 may extend over slot 58 so that the advancing needle slides along the flap toward the fitting, rather than entering the slot and engaging the suture directly. Flap 64 may be affixed along one side of the slot, with the other side of the flap flexing into the receptacle to release the suture from slot 58 when the fitting and suture are withdrawn by the needle.

An alternative mechanism for avoiding entanglement of the needle with the suture is illustrated 10B. In this embodiment, needle receptacles 52*i* have tangential slots 58*i* which extends substantially tangentially to the surface of the receptacle. As a result of this tangential arrangement, a needle entering the receptacle 52*i* will be directed toward the fitting contained therein, but will generally not be able to enter and advance

within the tangential slot 58*i* so as to become entangled with the suture. As illustrated in this embodiment, the slots may optionally extend laterally through the foot so that the loop of suture can be pulled from one side of the shaft without interference.

A still further alternative mechanism for avoiding entanglement between the suture and the needle is illustrated in Figs. 10C and D. Two-part needle 38*i* includes an outer sheath 66 and an inner core 68. The parts of these needles initially advance together into the receptacles with the needle core 68 withdrawn so that the needle presents a smooth tapered tip (the combined tip preferably being larger in diameter than the slot containing the suture) as illustrated in Fig. 10C. Once two-part needle 38*i* is fully positioned within the needle receptacle, needle core 68 may extend axially to expose barbed tip 42 and recessed engagement surface 44 and to secure the needle to the fitting within the needle receptacle. In the exemplary embodiment of Figs. 4 and 5, barbed tip 42 is formed integrally with the rest of the needle structure, but the tip has a larger cross-section than radial slot 58 containing the suture 34. As a result, the barbed tip is unable to enter the slot, thereby avoid entanglement between the needle and suture.

An alternative vessel closure probe 70 will be explained with reference to Figs. 11A through 11E. This embodiment includes an articulatable foot 24 having a pair of needle receptacles 52, as described above. Although each needle receptacle 52 contains a fitting 40 for coupling a flexible filament to a tip of an associated needle, the filament in this case comprises a short length of suture 74 (or some temporary connecting filament, as shown schematically in phantom in Fig. 11A) spanning directly between the needle receptacles. Rather than pulling the two ends of an extended loop through the needle paths and proximally out the tissue tract for tying, closure system 70 advances a single end of the suture distally along one needle path, across the puncture, and then proximally along the other needle path. To provide this interaction, at least one needle includes means for attaching suture 34 to short suture 74, here in the form of a detachable coupling structure carried on the at least one needle. This structure facilitates the use of a pre-tied knot.

Referring now to Figs. 11A and B, the distal end of probe 70 advances distally through skin S and into a tissue T of the patient while the probe is in the small profile configuration with foot 24 aligned along the axis of the probe. Here, however, an end 76 of suture 34 is affixed to a detachable needle tip 78 of a hollow needle 38'. Detachable tip 78 comprises a fitting having an opening receiving an end of suture similar



to fitting 40, attached to a barbed needle end (similar to that of needle 38). Suture 34 may extend proximally within hollow needle 38 where the needle has an open channel along its length, may exit the hollow needle just proximally of detachable tip 78, or may be disposed alongside a solid needle. Needle 38 (opposite hollow needle 38') has a fixed barbed tip, as described above, and a bight of suture 80 is releasably attached to the probe shaft encircling the opening of needle guide 54 of the fixed tip needle. The bight of suture may be releasably disposed within a slot of the probe, may be temporarily held in place by a weak adhesive or coating, or the like. A second end 82 of suture 34 extends proximally along the shaft of the probe, the second end of the suture optionally also being releasably held along the shaft.

Bight 80 will define a knot when first end suture passes therethrough, as can be understood with reference to Figs. 11Ai and 11Aii. Bight 80 will often include more than one loop, and may be pre-arranged so as to define a square knot (using the layout schematically illustrated in Fig. 11Ai), a clinch knot (Fig. 11Aii), or a variety of known or new surgical knots.

Probe 70 advances along tissue tract TT to puncture P in blood vessel V. Once foot 24 is disposed within a blood vessel V, a pull wire moves the foot proximally and pivots the foot laterally so that the foot extends along an axis A of the vessel, as illustrated in Fig. 11B. The foot can then be pulled proximally against an inner surface of the vessel wall W to ensure that the needle receptacles 52 are properly positioned.

As can be understood with reference to Figs. 11C and D, hollow needle 38' and needle 38 advance to engage fittings 40 within receptacles 52. Hollow needle 38' draws first end 76 of suture 34 distally through vessel wall W, and detachable tip 78 is secured into an associated fitting 40 using the barb and tab interaction described above.

As short suture 74 extends between fittings 40, and as detachable tip 78 can pull free of hollow needle 38' when the needles are withdrawn, this effectively couples needle 38 to first end 76 of suture 34. The detachable tip riding partially within the hollow needle (or vice versa) so that the assembly remains together under compression. Hence, needle 38 can pull the suture distally along the needle path formed by hollow needle 38', across the puncture P, and proximally along the needle path formed by needle 38, as illustrated in Fig. 11D.

Figs. 11D and E show that the knot can be completed by pulling needle 38, short suture 74, and second end 76 of suture 34 (together with the fittings 40 and

detachable needle tip 78) proximally through bight 80. Second end 82 of suture 34 can be pulled to free bight 80, and the ends of the suture can be tightened and the probe removed to provide permanent hemostasis.

It will be recognized that removal of probe 70 can be facilitated by coupling first end 76 to bight 80 over an outer surface of the probe, and by arranging suture 34 and hollow needle 38' so that the suture can pull free of the needle when detachable tip 78 is released, for example, by having the suture exit the needle proximally of the tip through a channel that extends to the tip so that the needle does not encircle the suture. By including such provisions, after foot 24 is returned to the narrow configuration, the probe can be pulled proximally from the tissue tract leaving the pre-tied knot in place.

Alternative arrangements (using the detachable needle ends of probe 70) are possible to provide the benefit of a pre-tied knot and the like for closure of a vessel puncture. For example, a probe having a pair of needles in which each needle included a detachable tip might be used to pull first end 76 through a bight, so that the bight need not encircle the needle path of one of the needles.

In some cases, particularly for closure of large punctures, it may be advantageous to provide multiple suture loops across the puncture, either in parallel, in an "X" pattern, or the like. As illustrated in Figs. 12A and B, the present invention encompasses the use of more than two needles and associated receptacles, fittings, sutures, and the like. Multiple loop systems may have four, six, eight, or more needles, or may even have odd numbers of needles and fittings, particularly where one or more fittings have a plurality of suture ends extending therefrom. This allows a wide variety of stitching patterns to be provided by such multiple loop probes.

The method of use of the probes of Figs. 1-7 can be understood with reference to Figs 13A-G. After accessing a blood vessel V (often using the Seldinger technique), a guidewire GW is left extending into skin S and down through tissue T along tissue tract TT. Guidewire GW enters vessel V through a puncture P in vessel wall W, and extends along the vessel throughout many endovascular procedures. As illustrated in Fig. 13A, distal guidebody 22 is advanced over the guidewire GW in a monorail fashion, so that the guidewire helps to direct the probe along the tissue tract TT and into the vessel through puncture P. Fig. 13B shows that when sensor 36 is disposed within the vessel,

blood can flow from the sensor port and through a lumen in shaft 12 to the proximal handle to notify the operator that foot 24 has been advanced far enough for deployment.

Deployment of the foot is effected by actuation of the foot deployment handle, as described and illustrated above with reference to Figs. 2 and 2B. As described above, guidebody 22 helps to align the probe with the axis of vessel V. Guidebody 22 may be set at an angle and/or offset relative to shaft 12 as appropriate to aid in alignment with a particular vessel access technique. As shown in Fig. 13C, the deployed foot 24 extends laterally from the shaft, so that foot 24 adjacent receptacles 52 can be drawn up against vessel wall W by gently pulling shaft 12. Hence, the foot helps to accurately position the needle guides 54 at a distance from the vessel wall.

Referring now to Fig. 13D, flexible needles 38 are deflected laterally by needle guides 54 toward receptacles 52 of the deployed foot. As a result, the needles advance in cantilever both distally and laterally when needle actuation handle 20 is pressed (see Fig. 2C), and the tapering surfaces of receptacles 52 help to push the needles back into alignment with the fittings so as to overcome any unintended deflection of the needles by tissue T or vessel wall W. This ensures that needles 38 securingly engage fittings 40 within receptacles 52, thereby coupling the ends of suture 34 to the needles. While suture 34 is here illustrated running along the side of shaft 12 outside foot receptacle 30 to a lumen within guidebody 22, it should be understood that the suture loop might instead extend proximally in a lumen of shaft 12, might be routed through the foot and/or foot receptacle, and/or might be stored in a spool adjacent foot 24. Regardless, suture 34 should be able to pull free of the probe between its ends to form a continuous loop across puncture P.

Referring now to Figs. 13E and F, fittings 40 and the ends of suture 34 are drawn proximally through the vessel wall W along the needle paths formed by needles 38. Optionally, the needles may be withdrawn proximally out of the tissue tract and clear of shaft 12, or they may remain coupled to the shaft within needle guides 54. The foot actuator is moved to store foot 24 along shaft 12, and the shaft can then be pulled proximally from the tissue tract. Guidebody 22, which may comprise a soft, compliant polymer, may temporarily extend at least partially into tissue tract TT and through puncture P to help reduce the loss of blood until the loop is secured.

Now referring to Fig. 13G, once shaft 12 has been withdrawn sufficiently to expose needle guides 54, the ends of the suture loop can be grasped by the operator.

Tying of a knot in suture 34 can then proceed in a conventional manner. The use of a clinch knot may facilitate gradual tightening of the knot while removing guidebody 22, although a wide variety of knot and knot advancing techniques might be used.

While the exemplary embodiments have been described in some detail for clarity of understanding, a wide variety of modifications, adaptations, and changes will be obvious to those of skill in the art. For example, some of the benefits of the present invention might be provided by actuating a foot disposed outside the blood vessel within the tissue tract, and advancing needles from within the blood vessel proximally through the vessel wall toward the actuated foot. Hence, the scope of the present invention is limited solely by the appended claims.

100 101 102 103 104 105 106 107 108 109 110 111 112 113 114 115 116 117 118 119 120 121 122 123 124 125 126 127 128 129 130 131 132 133 134 135 136 137 138 139 140 141 142 143 144 145 146 147 148 149 150 151 152 153 154 155 156 157 158 159 160 161 162 163 164 165 166 167 168 169 170 171 172 173 174 175 176 177 178 179 180 181 182 183 184 185 186 187 188 189 190 191 192 193 194 195 196 197 198 199 200 201 202 203 204 205 206 207 208 209 210 211 212 213 214 215 216 217 218 219 220 221 222 223 224 225 226 227 228 229 230 231 232 233 234 235 236 237 238 239 240 241 242 243 244 245 246 247 248 249 250 251 252 253 254 255 256 257 258 259 260 261 262 263 264 265 266 267 268 269 270 271 272 273 274 275 276 277 278 279 280 281 282 283 284 285 286 287 288 289 290 291 292 293 294 295 296 297 298 299 300 301 302 303 304 305 306 307 308 309 310 311 312 313 314 315 316 317 318 319 320 321 322 323 324 325 326 327 328 329 330 331 332 333 334 335 336 337 338 339 340 341 342 343 344 345 346 347 348 349 350 351 352 353 354 355 356 357 358 359 360 361 362 363 364 365 366 367 368 369 370 371 372 373 374 375 376 377 378 379 380 381 382 383 384 385 386 387 388 389 390 391 392 393 394 395 396 397 398 399 400 401 402 403 404 405 406 407 408 409 410 411 412 413 414 415 416 417 418 419 420 421 422 423 424 425 426 427 428 429 430 431 432 433 434 435 436 437 438 439 440 441 442 443 444 445 446 447 448 449 450 451 452 453 454 455 456 457 458 459 460 461 462 463 464 465 466 467 468 469 470 471 472 473 474 475 476 477 478 479 480 481 482 483 484 485 486 487 488 489 490 491 492 493 494 495 496 497 498 499 500 501 502 503 504 505 506 507 508 509 510 511 512 513 514 515 516 517 518 519 520 521 522 523 524 525 526 527 528 529 530 531 532 533 534 535 536 537 538 539 540 541 542 543 544 545 546 547 548 549 550 551 552 553 554 555 556 557 558 559 560 561 562 563 564 565 566 567 568 569 570 571 572 573 574 575 576 577 578 579 580 581 582 583 584 585 586 587 588 589 590 591 592 593 594 595 596 597 598 599 600 601 602 603 604 605 606 607 608 609 610 611 612 613 614 615 616 617 618 619 620 621 622 623 624 625 626 627 628 629 630 631 632 633 634 635 636 637 638 639 640 641 642 643 644 645 646 647 648 649 650 651 652 653 654 655 656 657 658 659 660 661 662 663 664 665 666 667 668 669 670 671 672 673 674 675 676 677 678 679 680 681 682 683 684 685 686 687 688 689 690 691 692 693 694 695 696 697 698 699 700 701 702 703 704 705 706 707 708 709 710 711 712 713 714 715 716 717 718 719 720 721 722 723 724 725 726 727 728 729 730 731 732 733 734 735 736 737 738 739 740 741 742 743 744 745 746 747 748 749 750 751 752 753 754 755 756 757 758 759 760 761 762 763 764 765 766 767 768 769 770 771 772 773 774 775 776 777 778 779 780 781 782 783 784 785 786 787 788 789 790 791 792 793 794 795 796 797 798 799 800 801 802 803 804 805 806 807 808 809 810 811 812 813 814 815 816 817 818 819 820 821 822 823 824 825 826 827 828 829 830 831 832 833 834 835 836 837 838 839 840 841 842 843 844 845 846 847 848 849 850 851 852 853 854 855 856 857 858 859 860 861 862 863 864 865 866 867 868 869 870 871 872 873 874 875 876 877 878 879 880 881 882 883 884 885 886 887 888 889 890 891 892 893 894 895 896 897 898 899 900 901 902 903 904 905 906 907 908 909 910 911 912 913 914 915 916 917 918 919 920 921 922 923 924 925 926 927 928 929 930 931 932 933 934 935 936 937 938 939 940 941 942 943 944 945 946 947 948 949 950 951 952 953 954 955 956 957 958 959 960 961 962 963 964 965 966 967 968 969 970 971 972 973 974 975 976 977 978 979 980 981 982 983 984 985 986 987 988 989 990 991 992 993 994 995 996 997 998 999 1000

WHAT IS CLAIMED IS:

1                   1.       A method for suturing a puncture through a vessel wall of a blood  
2 vessel, the puncture disposed within a tissue tract of a patient body, the method  
3 comprising:

4                   attaching a flexible filament to a first fitting;  
5                   inserting the first fitting through the tissue tract and positioning the first  
6 fitting adjacent the vessel wall;  
7                   forming a needle path by advancing a first needle through the vessel wall  
8 outside the puncture;  
9                   coupling the needle with the first fitting; and  
10                  withdrawing the first needle, the first fitting, and at least a first portion of  
11 the filament through the vessel wall along the needle path.

1                   2.       The method of claim 1, further comprising:  
2                   coupling the flexible filament to a second fitting;  
3                   positioning the second fitting adjacent the vessel wall so that the puncture  
4 is disposed between the first positioned fitting and the second positioned fitting;  
5                   advancing a second needle through the vessel wall and into engagement  
6 with the second fitting.

1                   3.       The method of claim 2, further comprising withdrawing the second  
2 needle and the second fitting through the vessel wall, wherein the filament coupling steps  
3 affix a first end of suture to the first fitting and a second end of the suture to the second  
4 fitting so that the withdrawing steps form a suture loop across the puncture.

1                   4.       The method of claim 3, wherein the withdrawing steps draw the  
2 suture from within the blood vessel out through the vessel wall.

1                   5.       The method of claim 2, wherein the first and second positioning  
2 steps comprise introducing the fittings through the puncture, and wherein the first and  
3 second needle advancing steps comprise inserting the needles into the vessel so as to  
4 engage the fittings therein.

1           6.       The method of claim 5, wherein the fittings are supported near a  
2       distal end of a shaft during the introducing step, and wherein the first and second  
3       positioning steps further comprise displacing the fittings laterally from the shaft.

1           7.       The method of claim 6, wherein the displacing step comprises  
2       articulating an elongate foot within the vessel so that the foot moves from a low profile  
3       configuration aligned along the shaft to a deployed configuration extending laterally from  
4       the shaft and along the blood vessel, the fittings being releasably mounted near first and  
5       second ends of the foot.

1           8.       The method of claim 7, further comprising pulling the deployed  
2       foot proximally against an interior surface of the vessel wall after the deploying step.

1           9.       The method of claim 8, further comprising verifying that the foot is  
2       disposed within the vessel prior to the displacing step by monitoring a sensor adjacent the  
3       foot.

1           10.      The method of claim 7, wherein the articulating step comprises  
2       sliding at least a portion of the foot axially along the shaft.

1           11.      The method of claim 7, wherein the articulating step comprises  
2       pivoting the foot away from an axial orientation.

1           12.      The method of claim 2, wherein the second advancing step passes  
2       suture through the vessel wall and couples the suture to the second fitting.

1           13.      The method of claim 12, wherein the withdrawing step draws the  
2       first fitting, the filament, the second fitting, and a portion of the suture through the vessel  
3       wall along a needle path of the first needle.

1           14.      The method of claim 13, further comprising forming a loop of the  
2       suture, wherein the withdrawing step draws the portion of the suture through the loop to  
3       help form a suture knot.

1           15.      The method of claim 1, wherein the first fitting defines an opening  
2       and a latch, and further comprising attaching the fitting to the needle by latching the  
3       needle into the opening of the fitting.

1                   16.     The method of claim 15 wherein the needle has a recess and the  
2 fitting comprises a substantially cylindrical cuff having at least one tab extending therein,  
3 and wherein the advancing step deflects the at least one tab when the needle is received in  
4 the opening, the at least one tab resiliently flexing into the recess to secure the fitting to  
5 the needle.

1                   17.     The method of claim 15, further comprising directing a needle into  
2 the opening with a guide surface around the opening, the needle being flexible.

1                   18.     The method of claim 1, wherein the first needle withdraws said at  
2 least a portion of the flexible element without threading the flexible element into the  
3 needle.

1                   19.     A method for suturing an opening in a tissue, the method  
2 comprising:  
3                   inserting a distal end of a probe through the opening, the probe defining a  
4 probe axis;  
5                   articulating an elongate foot of the probe so that first and second ends of  
6 the foot extend laterally with the opening aligned therebetween;  
7                   forming a first needle path from the probe through the tissue and to the  
8 first end of the foot;  
9                   forming a second needle path from the probe through the tissue and to the  
10 second end of the foot;  
11                  advancing suture along the first and second needle paths to position a  
12 suture loop across the opening.

1                   20.     The method of claim 19, wherein the tissue comprises a blood  
2 vessel having an axis, wherein the articulating step is performed so that the articulated  
3 foot extends along the vessel axis within the vessel.

1                   21.     The method of claim 19, wherein the first and second needle path  
2 forming steps comprise deflecting first and second flexible needles at an angle relative to  
3 the probe axis and advancing the needles in cantilever radially outwardly from first and  
4 second fixed needle guides of the probe to the first and second ends of the articulated

foot, the first and second ends of the articulated foot being separated laterally relative to the probe axis by a greater distance than the first and second needle guides.

22. The method of claim 19, wherein the articulating step comprises pulling a flexible element proximally so that the flexible element slides the foot proximally along the probe axis and so that the foot pivots laterally within the blood vessel.

23. The method of claim 19, further comprising inserting the foot through the puncture prior to the articulating step and pulling the shaft proximally after the articulating step so that the first and second ends of the deployed foot firmly engage the tissue beyond the puncture.

24. A method for suturing a blood vessel, the vessel having a vessel wall, the method comprising:

advancing a shaft toward the vessel wall, the shaft having an axis and a plurality of needle guides;

deploying a foot adjacent the vessel wall so that the foot extends laterally from the shaft;

advancing a plurality of needles from needle guides of the shaft to the foot to form needle paths through the vessel wall, the needle guides deflecting the needles laterally so that a needle path width is greater than a cross-sectional dimension of the shaft; and

advancing suture along the needle paths to position at least one suture loop across the puncture.

25. The method of claim 24, wherein the needles are flexible and the needle guides are fixed, and further comprising directing the needles laterally into secure engagement with fittings disposed releasably on the foot with a tapering needle receptacle surface of the foot.

26. A method for suturing a puncture of a blood vessel through a tissue tract of a patient body, the vessel having a vessel wall, the method comprising:

inserting a distal end of the probe through the puncture and into the blood vessel;



5                   advancing a first end of the suture from the probe within the tissue tract,  
6 through the vessel wall, and into the vessel;

7                   withdrawing the first end of the suture from the vessel, through the vessel  
8 wall and through a bight of the suture to form a loop of suture across the puncture; and

9                   tensioning the first end of the suture and a second end of the suture  
10 adjacent the bight to form a knot affixing the loop of suture across the puncture.

1                 27.     The method of claim 26, further comprising releasably attaching  
2 the bight of suture to a probe before the inserting step, wherein the tensioning step  
3 detaches the bight from the probe.

1                 28.     A system for suturing a blood vessel, the vessel having a vessel  
2 wall, the system comprising;

3                   a needle having a proximal end and a distal end suitable for forming a  
4 needle path through the vessel wall, the needle having a recessed engagement surface  
5 adjacent the distal end;

6                   a flexible filament; and

7                   a fitting attached to the filament, the fitting having an opening and at least  
8 one tab extending into the opening, the tab securingly engaging the engagement surface  
9 when the needle advances through the vessel wall and into the opening so that the fitting  
10 and at least a portion of the filament can be withdrawn proximally along the needle path  
11 by the needle.

1                 29.     The system of claim 28, wherein the at least one tab resiliently  
2 deflects into an indentation adjacent the engagement surface when the needle advances  
3 into the opening.

1                 30.     The system of claim 29, wherein the fitting comprises a tube  
2 having a proximal end and a distal end, the opening extending into the proximal end, the  
3 at least one tab formed of tube material by cutting slots through the tube, wherein the  
4 filament comprises suture extending distally from the distal end of the tube.

1                 31.     The system of claim 30, wherein the fitting further comprises a  
2 collar disposed about the suture, the collar crimped over an end of the suture.

1           32.     The system of claim 28, wherein the fitting is mounted on a foot  
2 near a distal end of a probe, the probe having a handle near a proximal end of the probe,  
3 actuation of the handle effecting articulation of the foot so that the fitting moves laterally  
4 from an axis of the probe.

1           33.     The system of claim 28, wherein the needles are flexible, and  
2 wherein the fitting is releasably supported within a receptacle surface oriented to laterally  
3 deflect the advancing needle toward the fitting.

1           34.     The system of claim 33, wherein the receptacle surface tapers from  
2 a small cross-section adjacent the fitting to a large cross-section oriented toward the  
3 advancing needle.

1           35.     The system of claim 33, further comprising a slot disposed along  
2 the receptacle surface, wherein the filament is releasably disposed in the slot, the slot  
3 configured to avoid engagement of the needle with the suture.

1           36.     The system of claim 35, wherein the slot has a cross-section  
2 smaller than the needle.

1           37.     A system for suturing a puncture of a blood vessel within a tissue  
2 tract, the vessel having a vessel wall and defining an axis, the system comprising:

3                 a shaft having a proximal handle and a distal end suitable for insertion  
4 along the tissue tract and into the vessel through the puncture;

5                 a foot mounted near the distal end of the shaft, the foot having a plurality  
6 of needle receptacles extendable laterally from the shaft;

7                 a flexible filament extending between the needle receptacles of the foot;

8                 a plurality of needles advanceable distally and laterally from the shaft,  
9 through the vessel wall outside the puncture, and to the needle receptacles of the foot.

1           38.     The system of claim 37, further comprising a plurality of fittings  
2 disposed adjacent the receptacles of the foot, the fittings securingly engaging the needles  
3 so that the needles, fittings, and at least a portion of the filament can be withdrawn  
4 through the vessel wall along at least one of the needle paths formed by the needles  
5 without threading the filament into the needles.

1           39.     The system of claim 37, wherein the foot comprises an elongate  
2 body defining an axis, the foot articulatable from a small profile configuration to a large  
3 profile configuration by actuating the proximal handle so that the foot slides axially and  
4 pivots laterally within the vessel.

1           40.     A system for suturing a puncture of a blood vessel within a tissue  
2 tract, the vessel having a vessel wall, the system comprising:

3                 a shaft having a proximal handle and a distal end suitable for insertion  
4 along the tissue tract and into the vessel through the puncture;

5                 a foot mounted near the distal end of the shaft, the foot having a first  
6 needle receptacle and articulatable from a small profile configuration to a large profile  
7 configuration by actuation of the handle;

8                 a first fitting removably mounted adjacent the first needle receptacle;  
9                 filament coupled to the first fitting; and

10                a first needle advanceable from the shaft to the first needle receptacle on  
11 the articulated foot, the first fitting securely engaging the first needle so that the secured  
12 first fitting and at least a portion of the filament can be withdrawn through the vessel wall  
13 by the first needle.

1           41.     The system of claim 40, wherein the filament comprises a suture  
2 and couples the first fitting to a second fitting, and further comprising a second receptacle  
3 disposed near the distal end of the shaft and a second needle advanceable from the shaft  
4 to the receptacle to withdraw the second fitting proximally through the vessel wall and  
5 form a suture loop across the puncture.

1           42.     The system of claim 40, further comprising a second receptacle  
2 disposed near the distal end of the shaft, a second fitting coupled to the filament and  
3 disposed within the second receptacle, a second needle adapted to form a second needle  
4 path through the vessel wall and having a suture releasably mounted thereon, wherein the  
5 second fitting couples the filament to the suture so that the suture can be withdrawn  
6 proximally along a first needle path through the vessel wall formed by the first needle to  
7 form a suture loop across the puncture.

1           43.     The system of claim 42, wherein a loop is releasably supported  
2     about a first needle port, the first needle advancing from the first needle port so that  
3     tensioning the withdrawn suture secures a knot in the suture loop.

1           44.     The system of claim 40, further comprising a sensor near the distal  
2     end of the shaft to indicate when the shaft extends into the vessel, and wherein the  
3     deployed foot can engage an inner surface of the vessel wall when the shaft is withdrawn  
4     proximally to help axially position the shaft.

1           45.     A probe for suturing an opening in a tissue, the probe comprising:

2                 a shaft having a proximal end and a distal end and defining an axis  
3     therebetween, the shaft having a size and configuration suitable for insertion through the  
4     opening in the tissue;

5                 an elongate foot movably mounted to the shaft;

6                 an actuator extending along the shaft distally to the foot, movement of the  
7     actuator sliding the foot axially and pivoting the foot from a low profile configuration  
8     aligned along the shaft to a deployed configuration extending laterally from the shaft;

9                 a suture supported by the foot; and

10                a needle advanceable from the shaft through the tissue and to the deployed  
11     foot.

1           46.     The probe of claim 45, wherein the foot has a first end and a  
2     second end, and wherein a plurality of needles are extendable from the shaft to the ends  
3     of the foot.

1           47.     The probe of claim 46, wherein a first length of suture extends  
2     between a first fitting at the first end of the probe to a second fitting at the second end of  
3     the probe, and wherein a second length of suture extends from a third fitting at the first  
4     end of the probe to a fourth fitting at the second end of the probe, and wherein each fitting  
5     securingly engages an associated needle to draw ends of the first and second length of  
6     suture through the vessel wall and form a plurality of loops across the puncture.

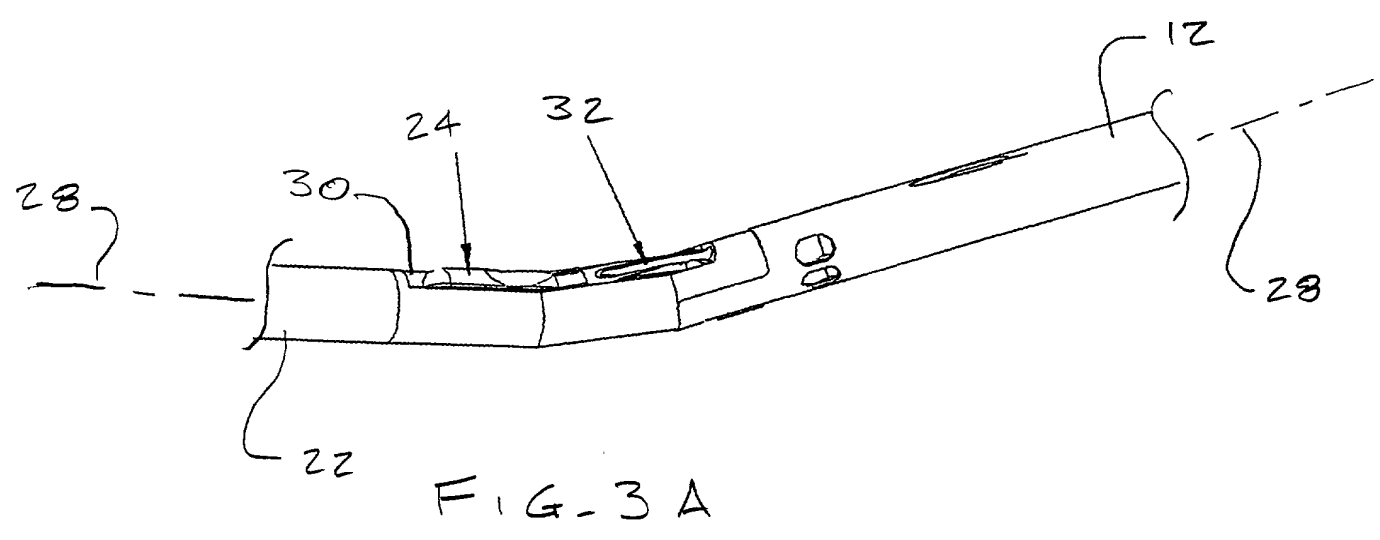
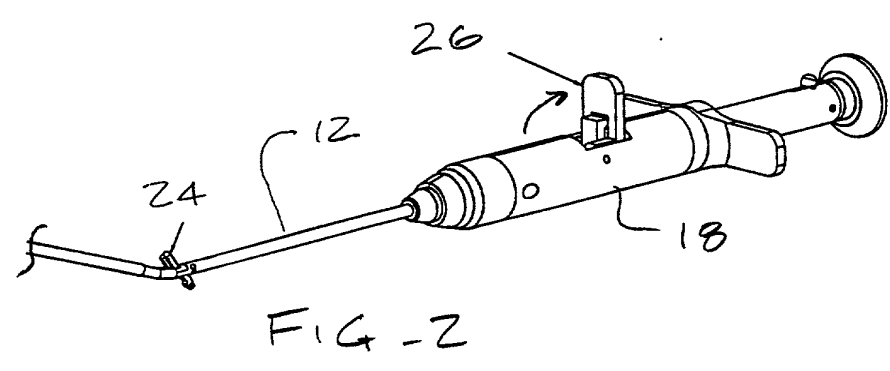
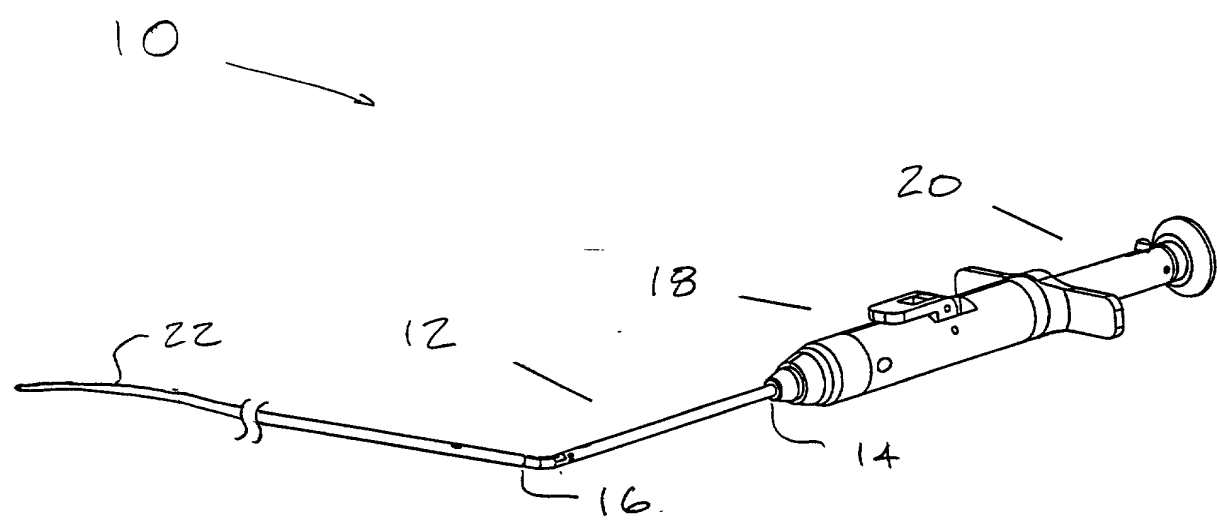
## ARTICULATING SUTURING DEVICE AND METHOD

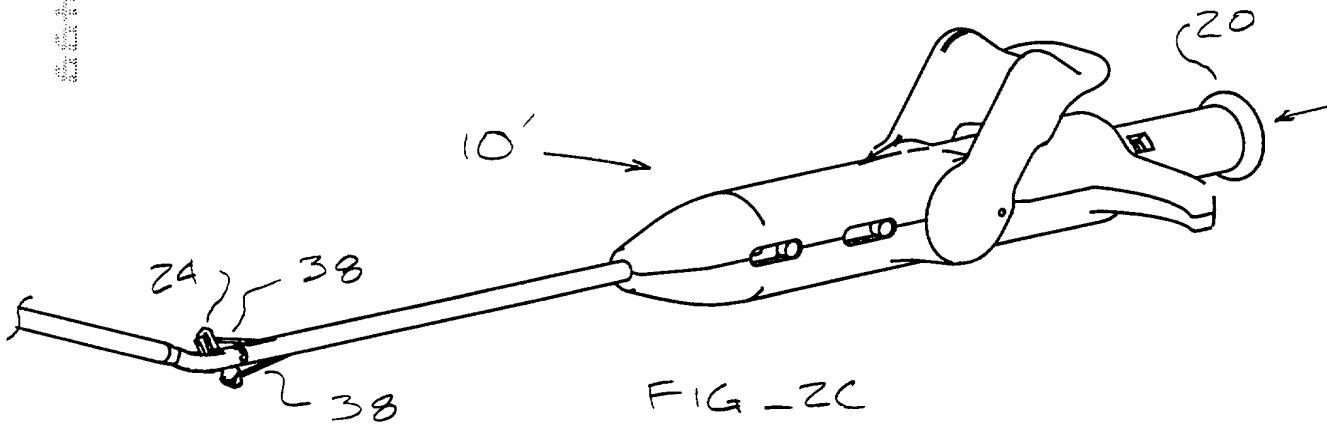
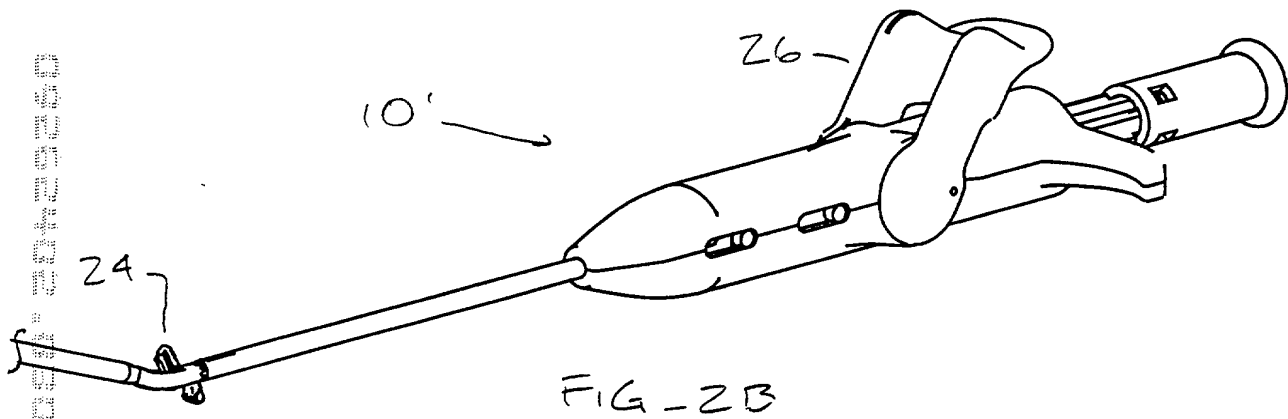
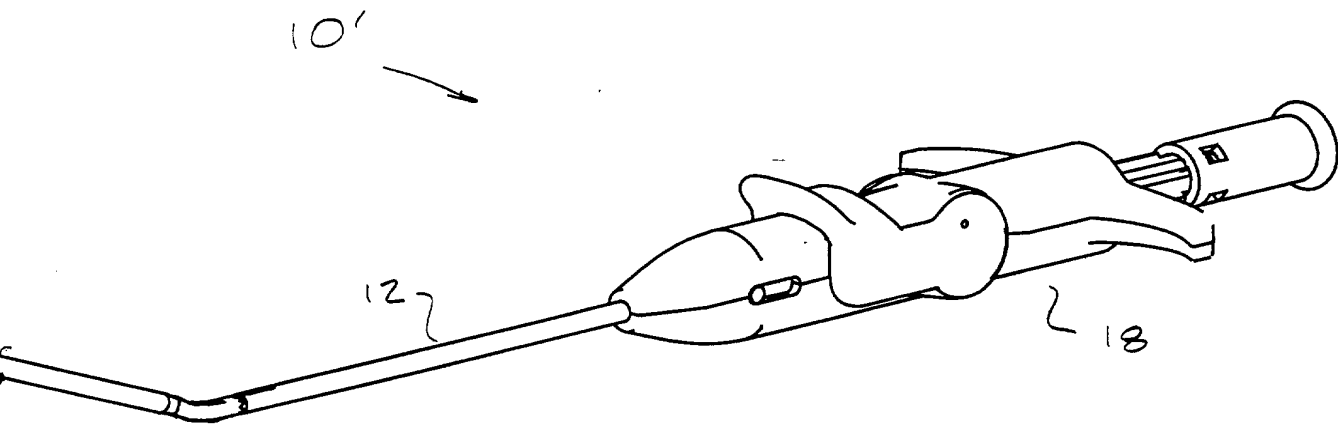
## ABSTRACT OF THE DISCLOSURE

Devices, systems, and methods for suturing of body lumens allow the suturing of vascular puncture sites located at the distal end of a percutaneous tissue tract.

An elongated articulated foot near a distal end of a shaft is inserted through the

5 penetration and actuated so that the foot extends along the luminal axis. The foot carries suturing attachment cuffs, and needles are advanced from the shaft through the vessel wall outside of the penetration and into engagement with the needle cuffs after the foot has been drawn proximally up against the endothelial surface of the blood vessel. The cross-section of the shaft within the tissue tract can be minimized by laterally deflecting  
10 the needles as they leave the shaft, while tapered depressions within the foot can guide the advancing needles into engagement with the cuffs. The cuffs lockingly engage the needles and can be withdrawn proximally along the needle paths and through the tissue tract so as to form a loop of suture across the puncture. The articulating foot may be realigned with the shaft and withdrawn proximally through the tissue tract without  
15 dilating the tissue tract.





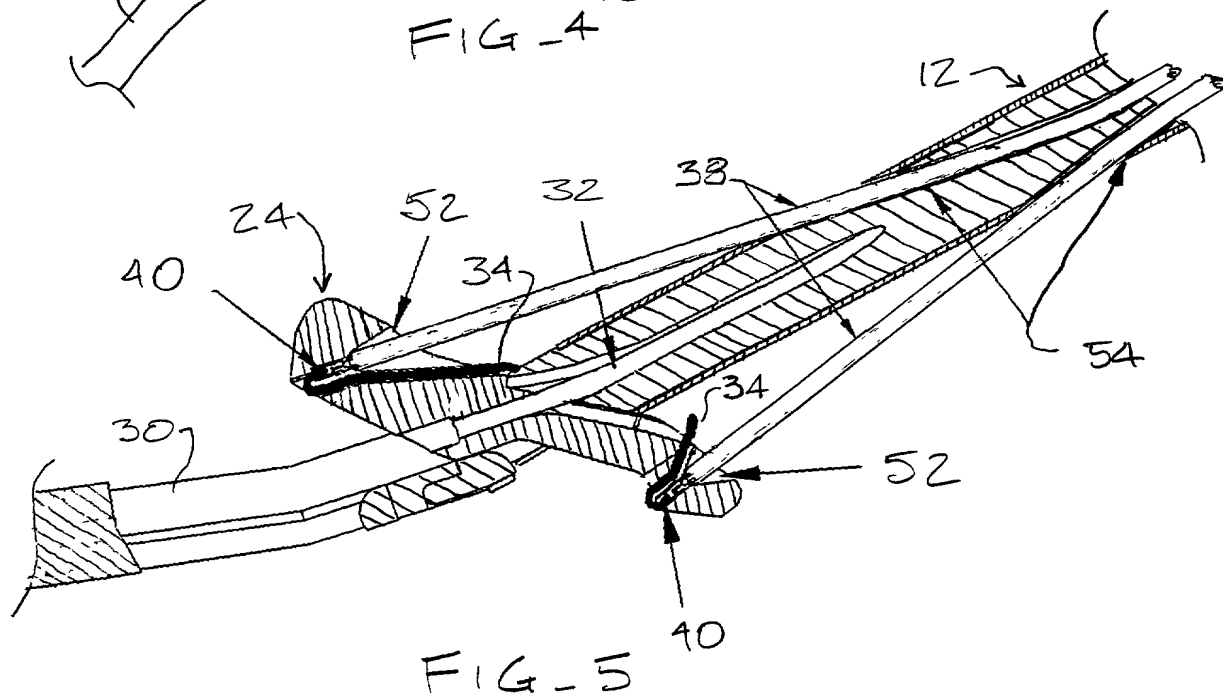
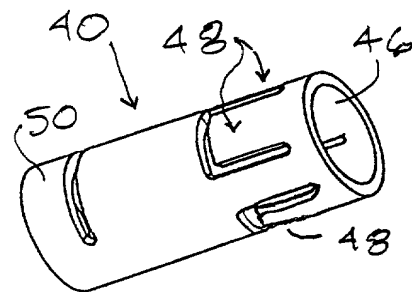
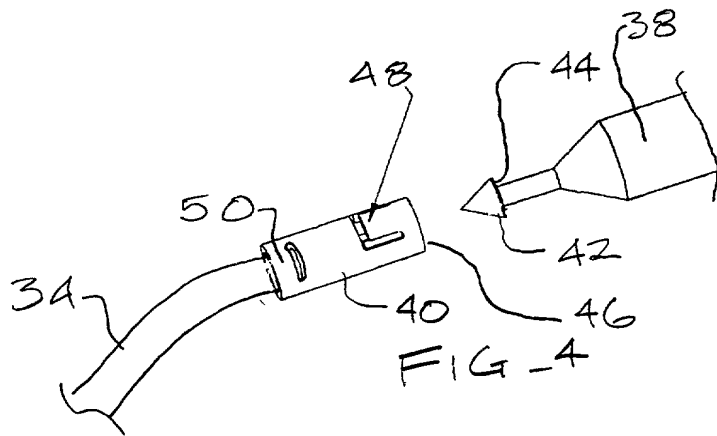
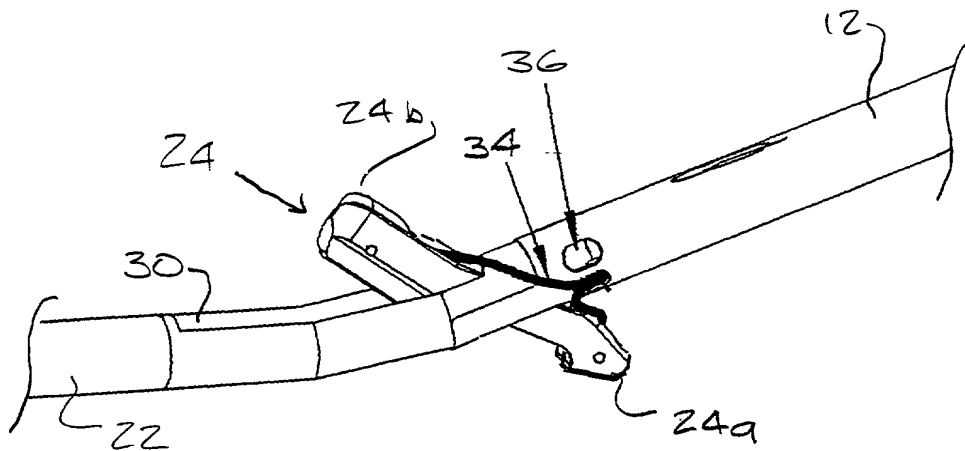




FIG 6A

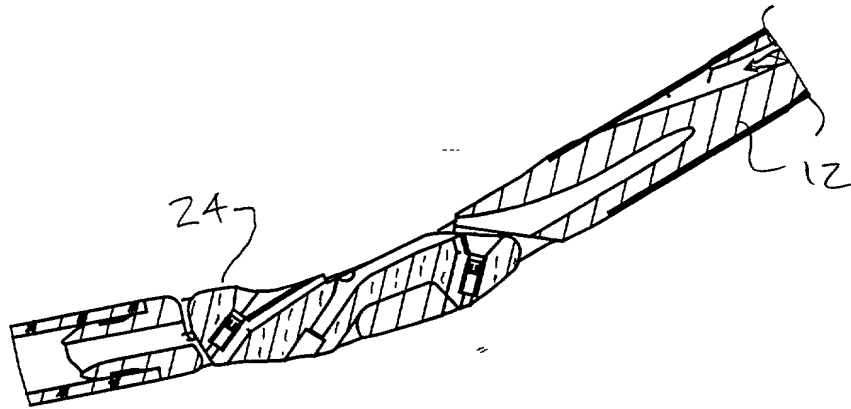


FIG-6B

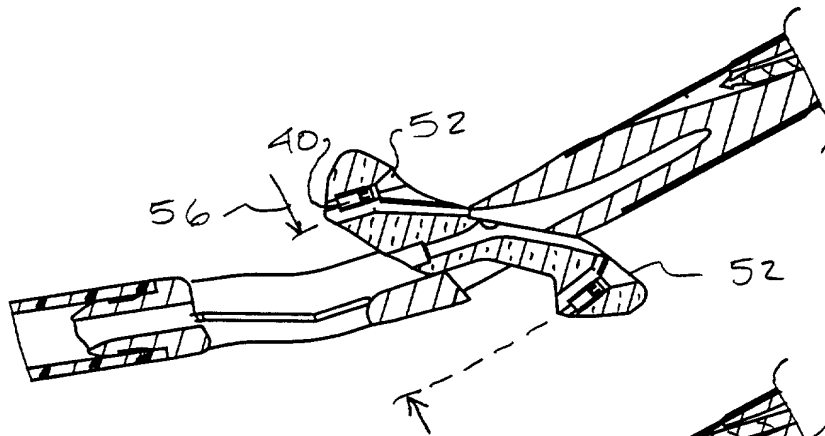


FIG-6C

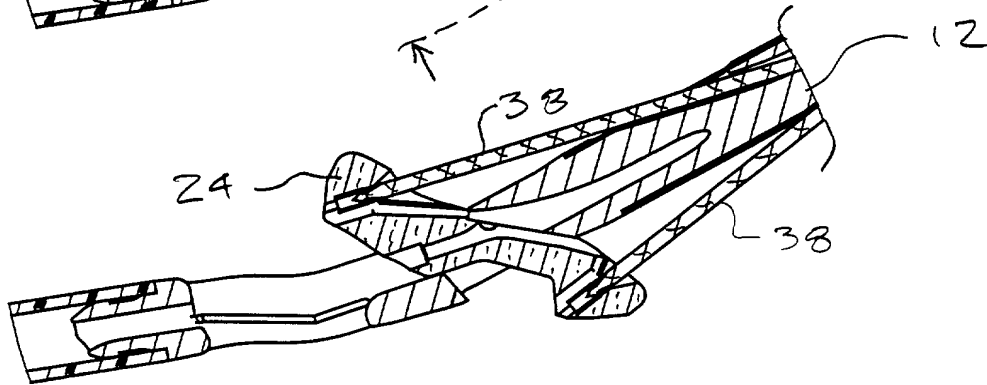
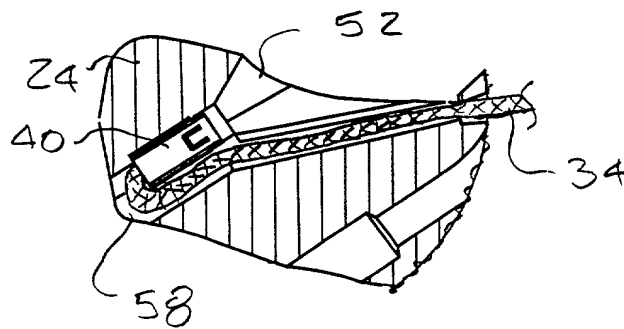


FIG - 7



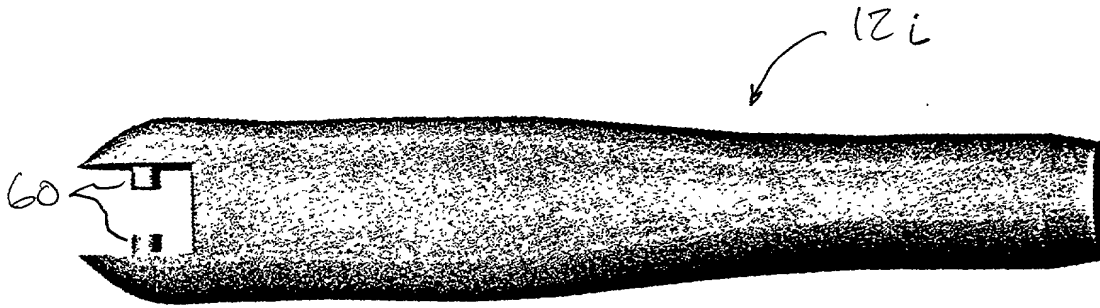


FIG-8A

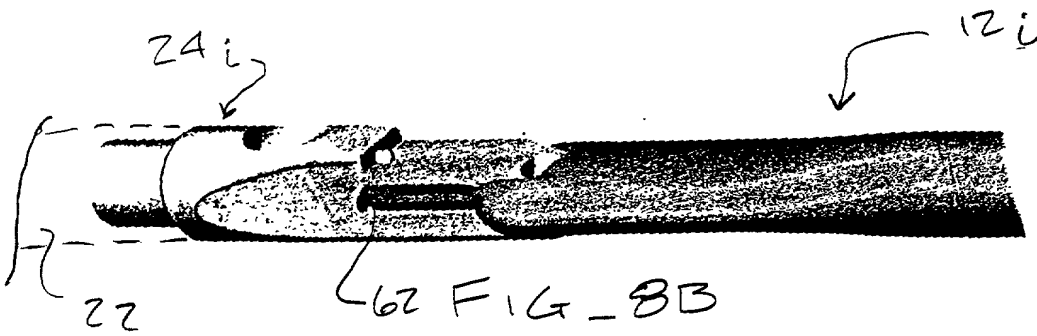


FIG-8B

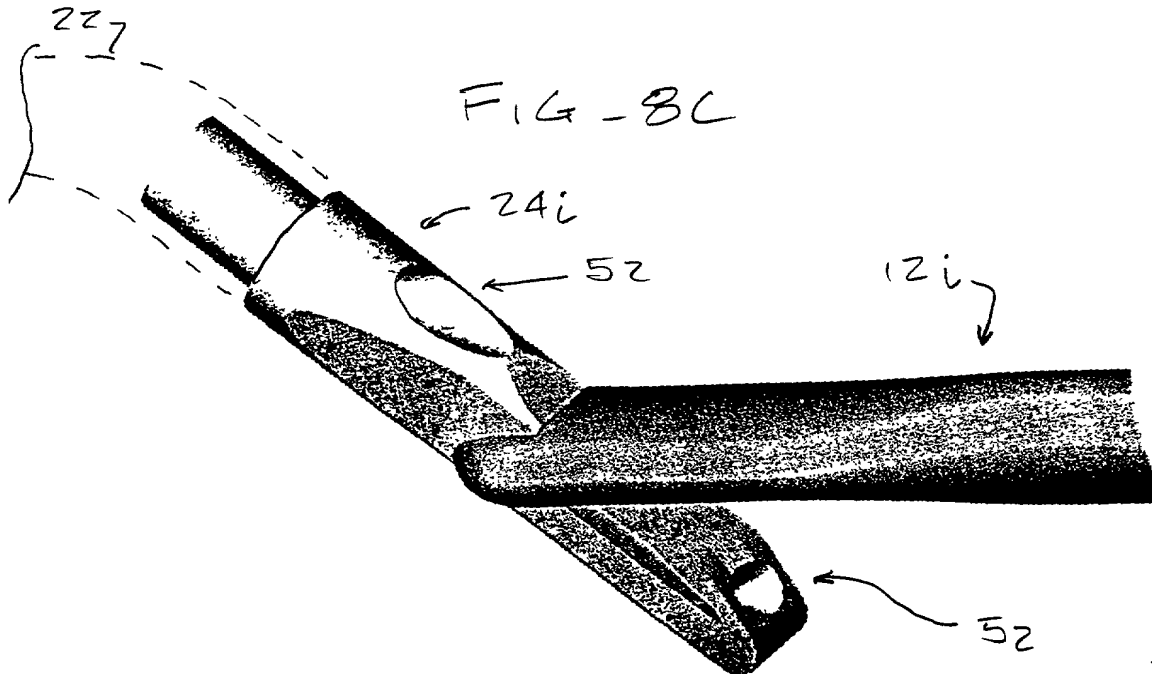


FIG-8C

FIG-9A

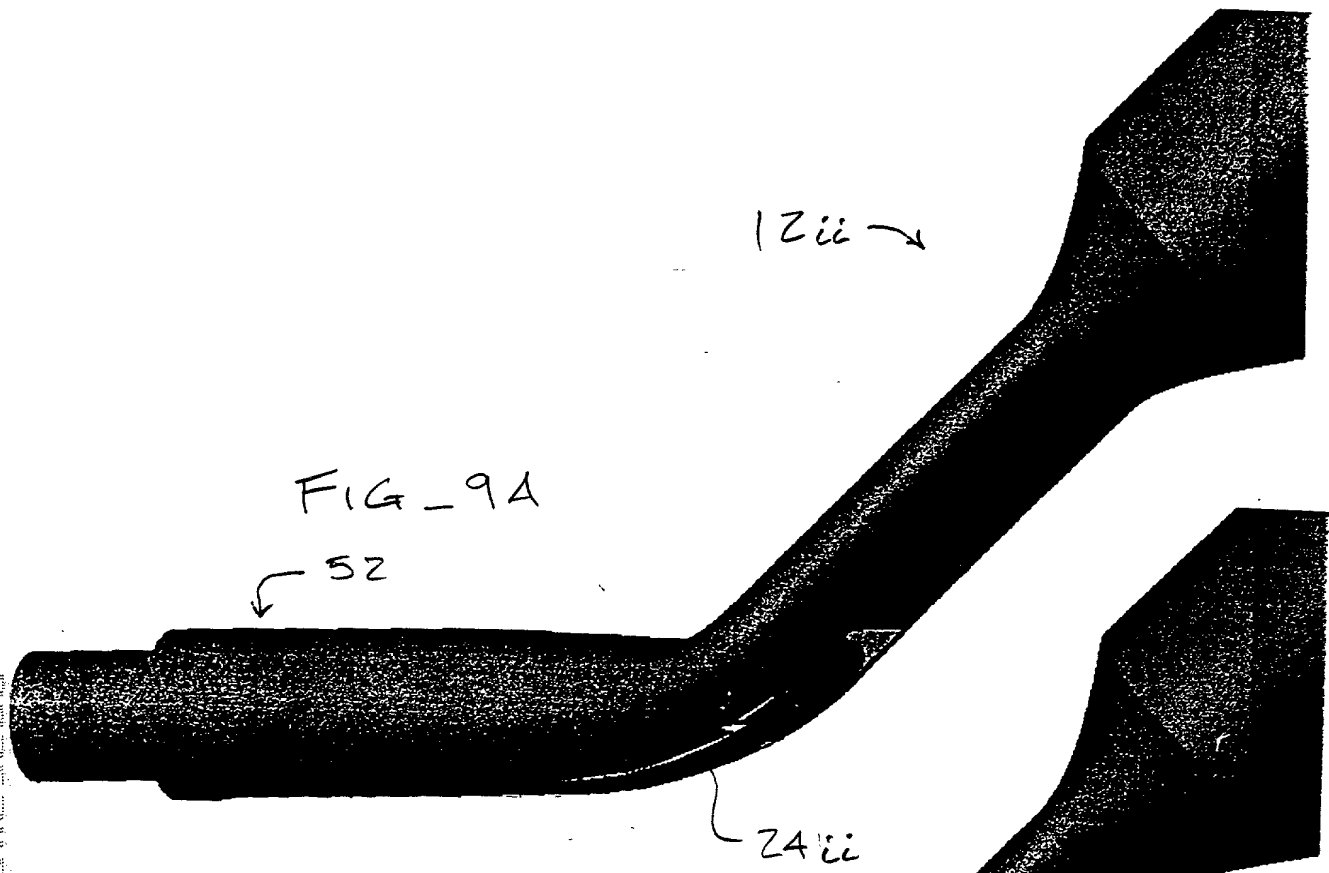
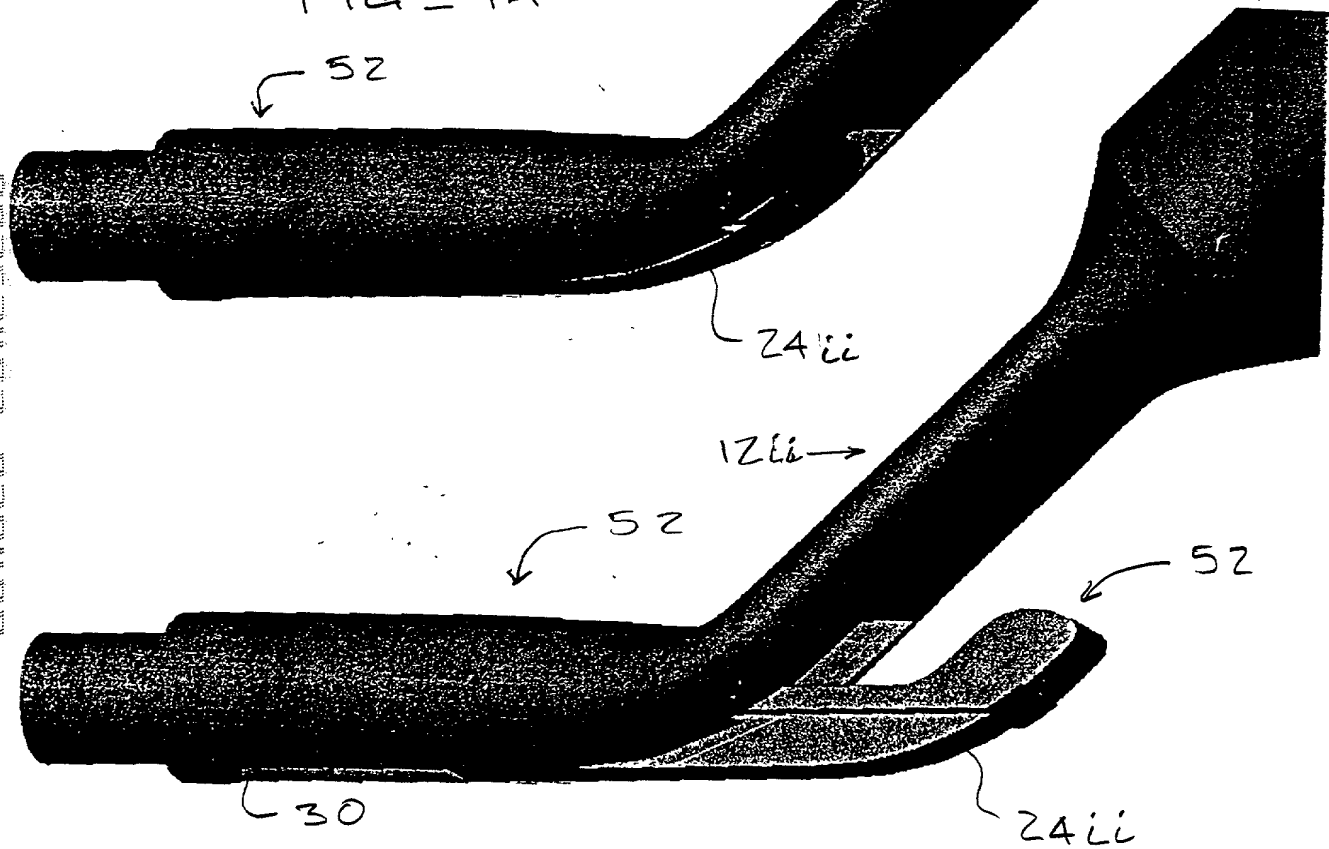
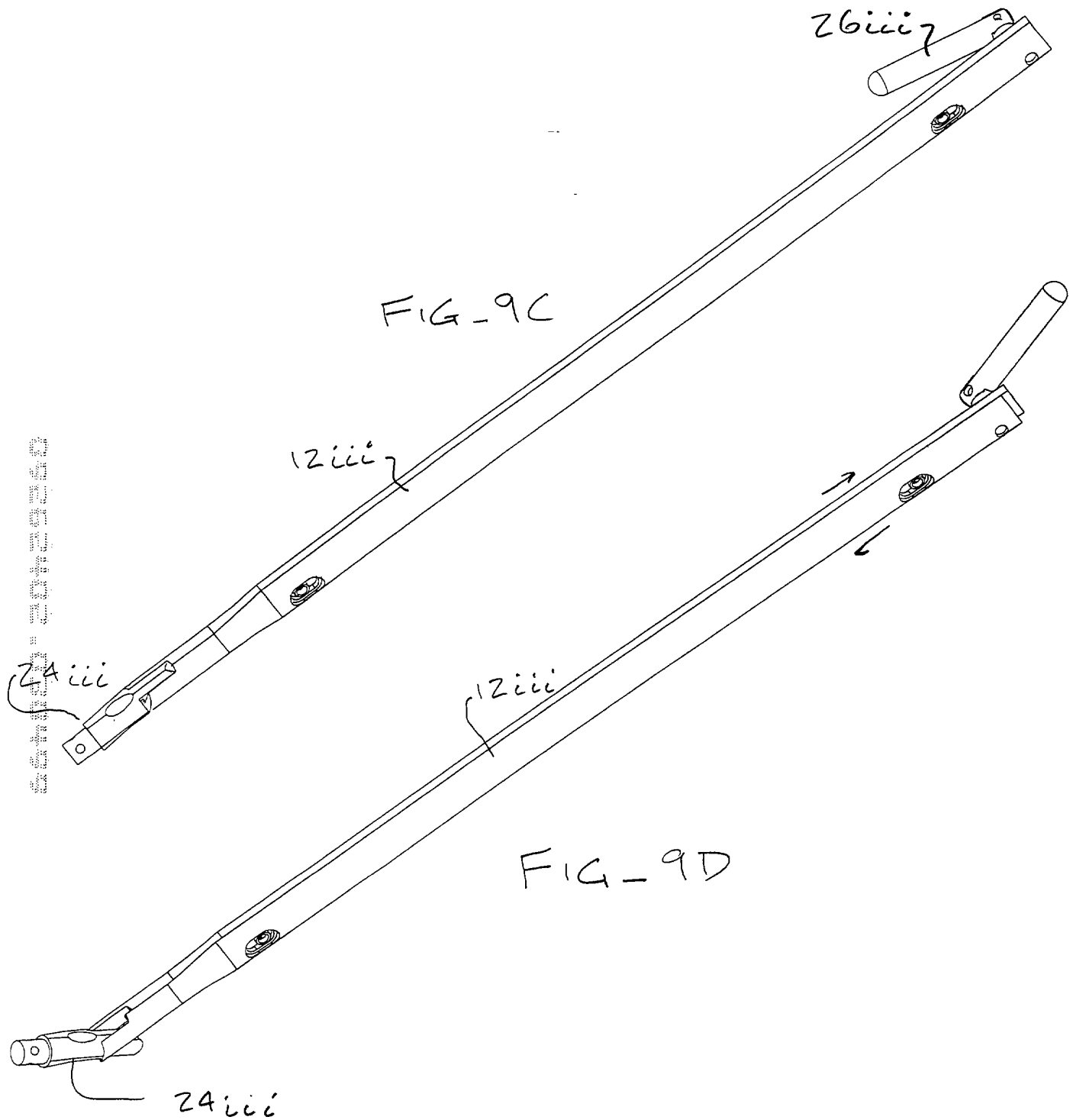


FIG-9B





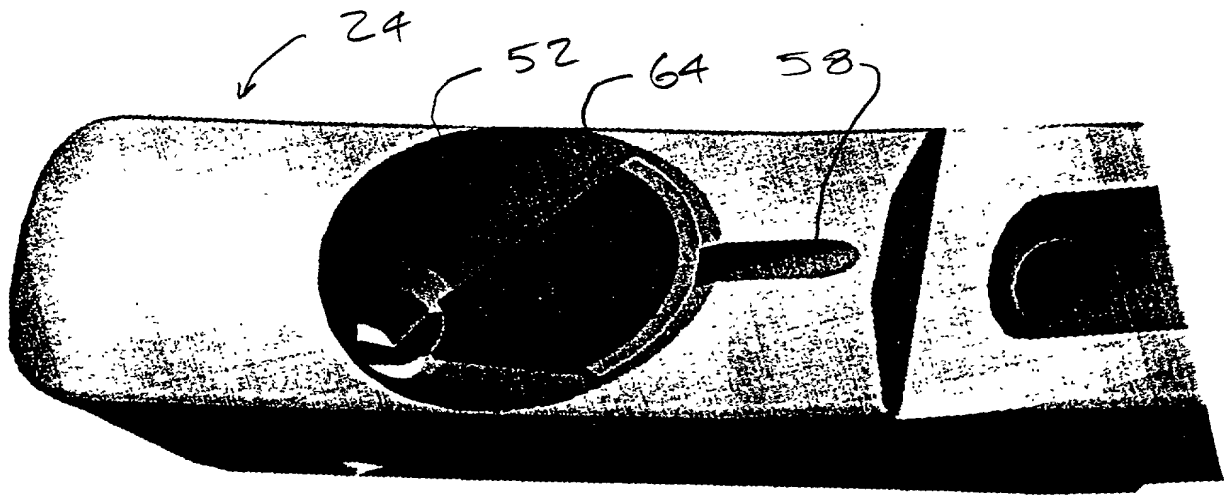


FIG-10A

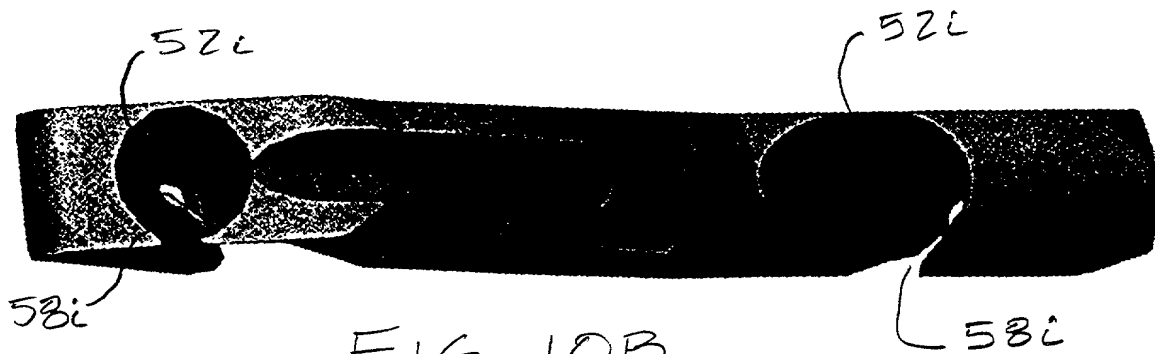


FIG-10B

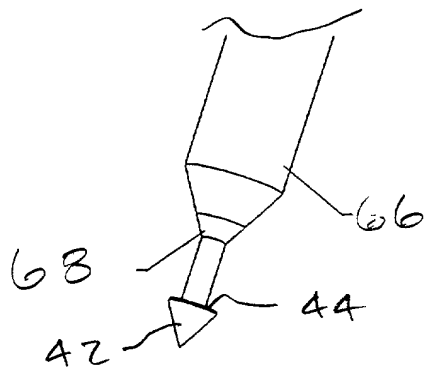


FIG-10D

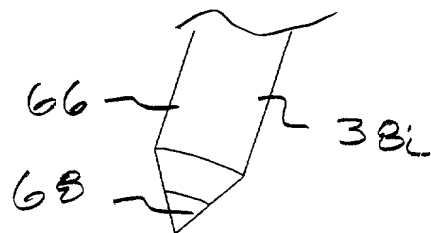


FIG-10C

FIG. 11A

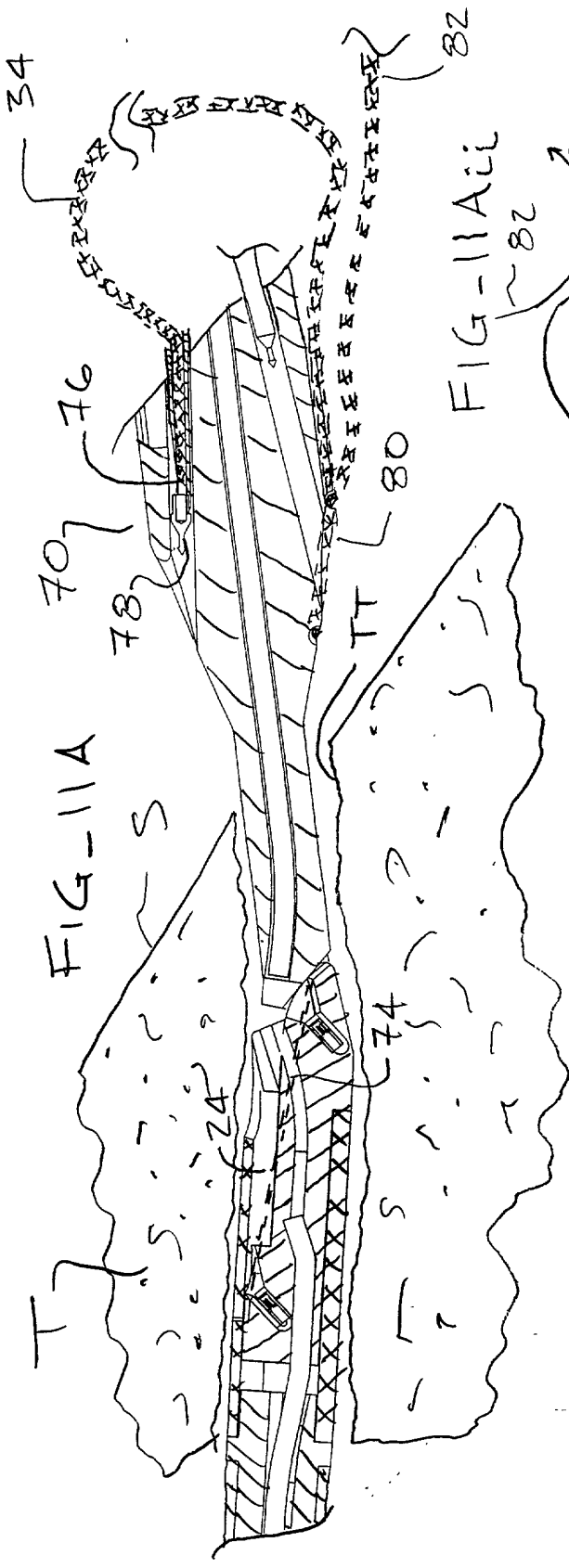


FIG-11Aii



FIG-11Ai

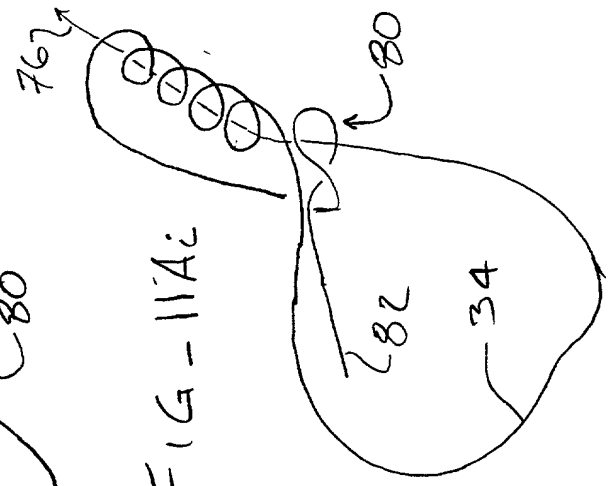
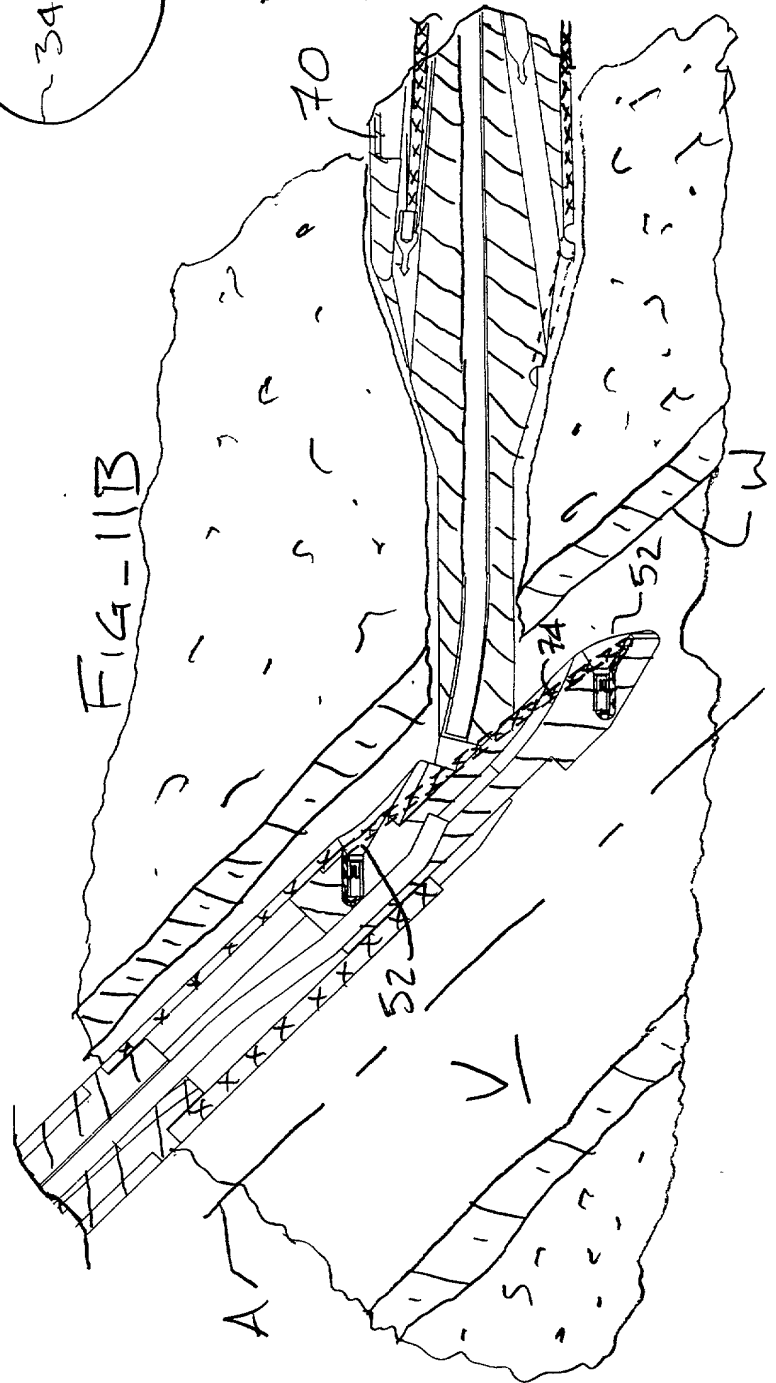
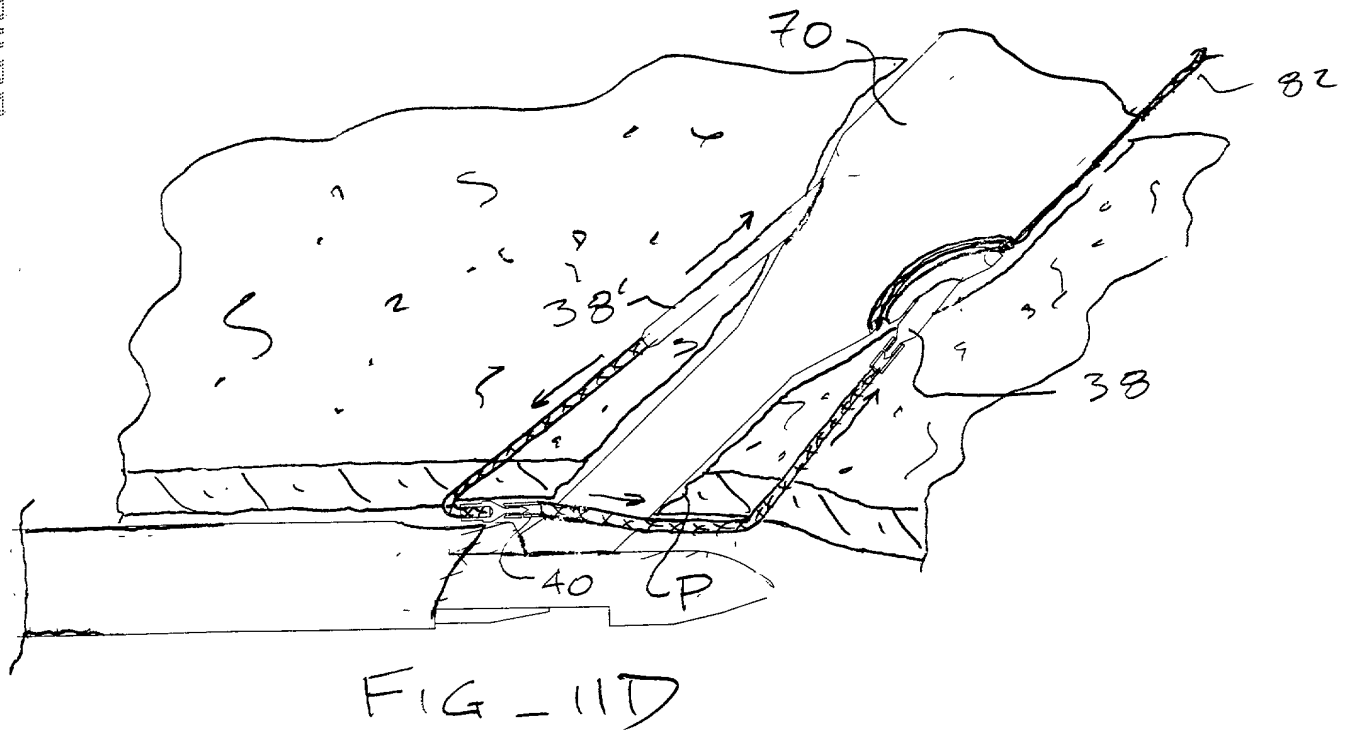
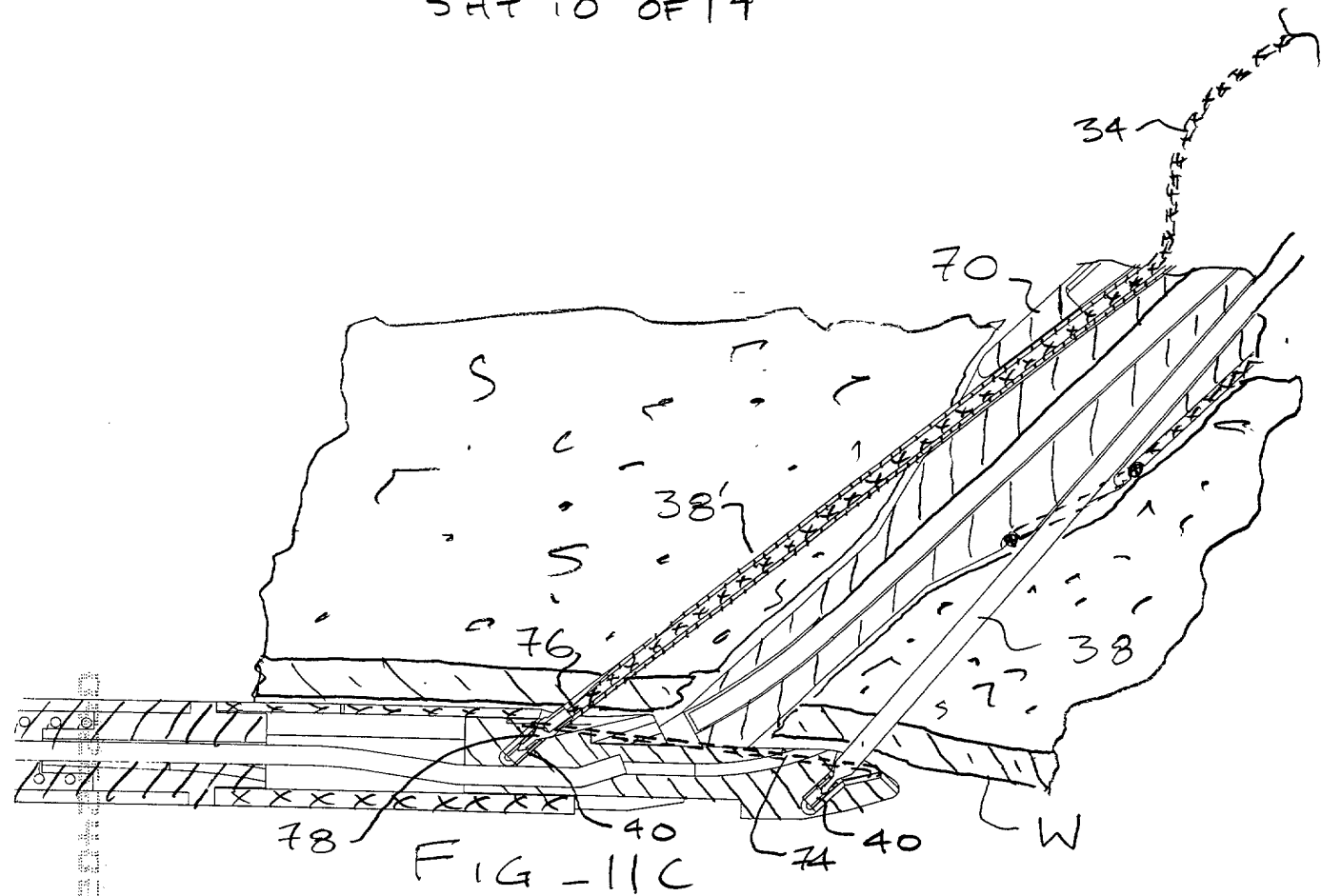


FIG-11B





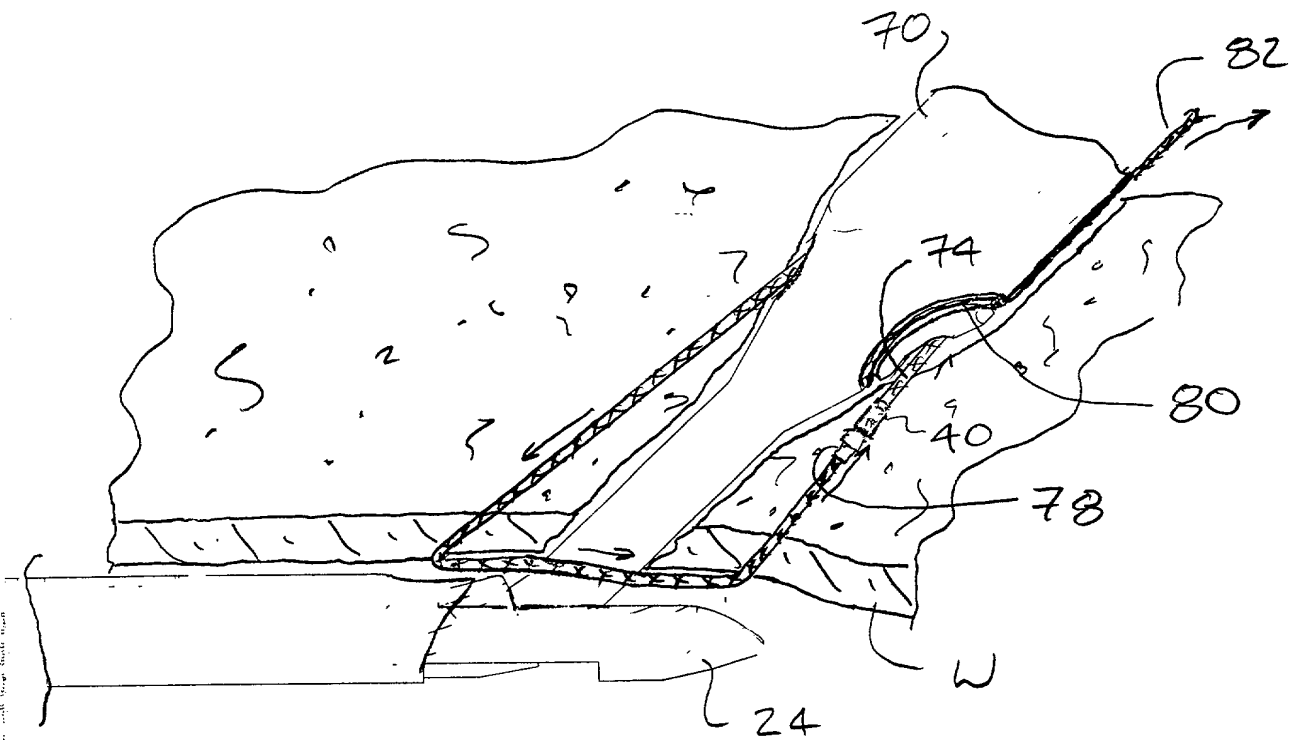


FIG - 11E

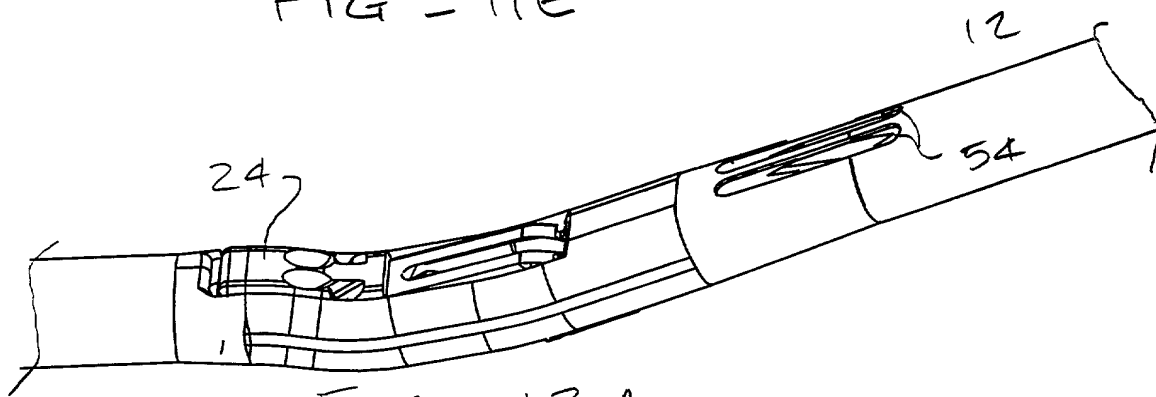


FIG - 12A

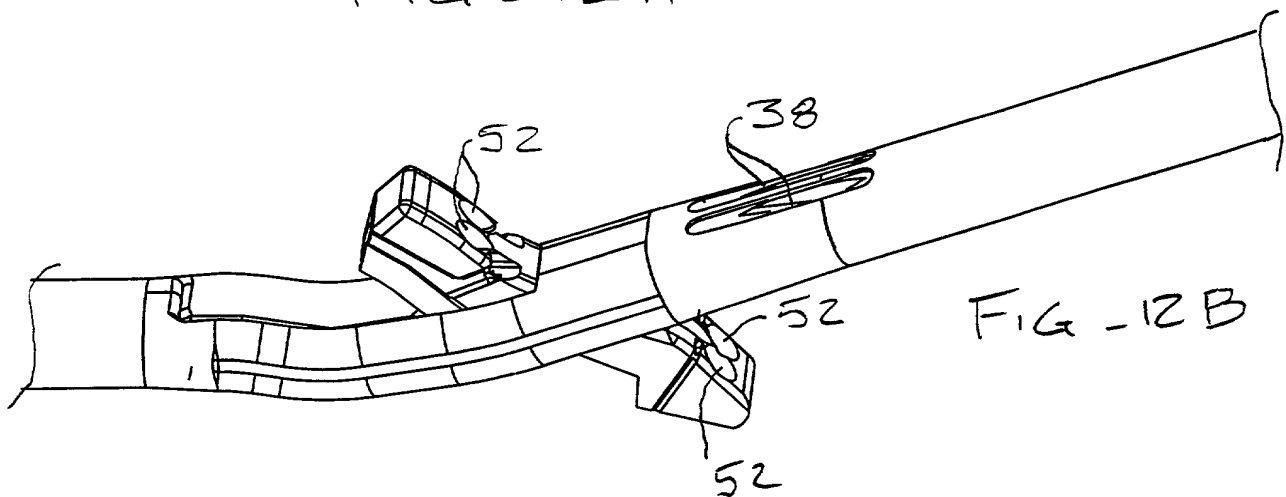


FIG - 12B



FIG-13A

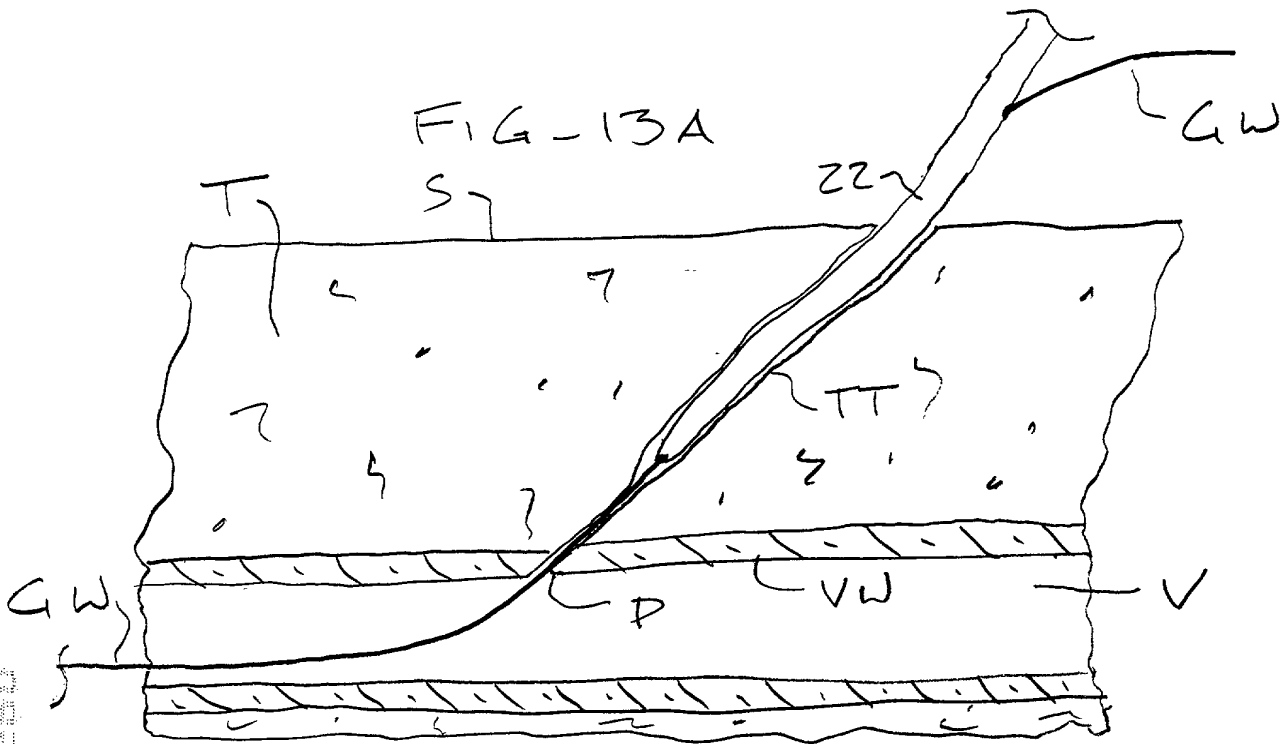


FIG-13B

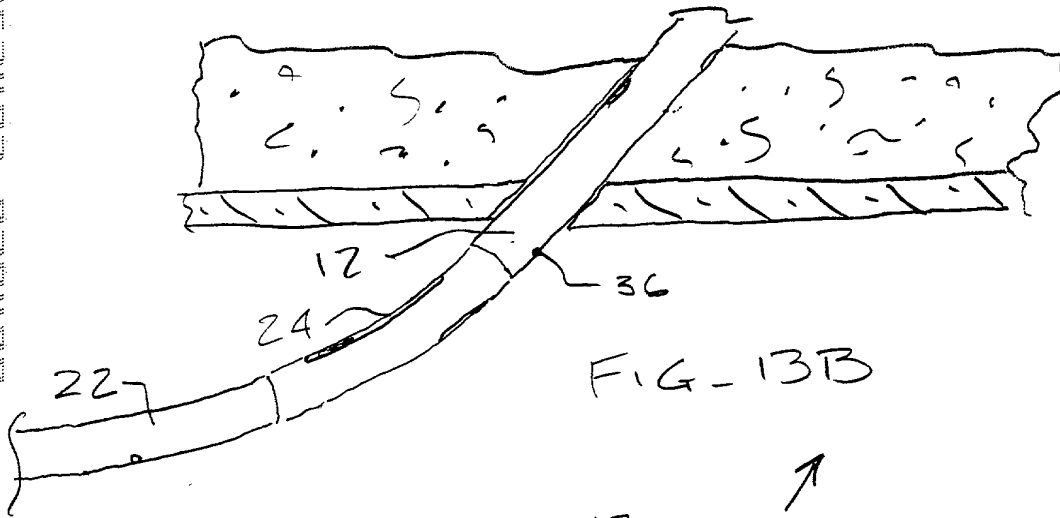
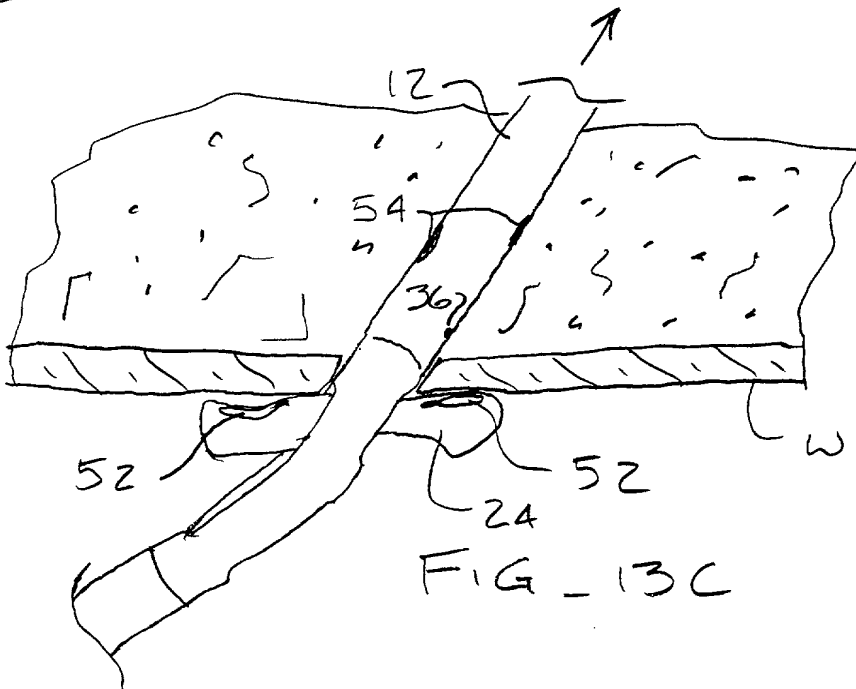


FIG-13C



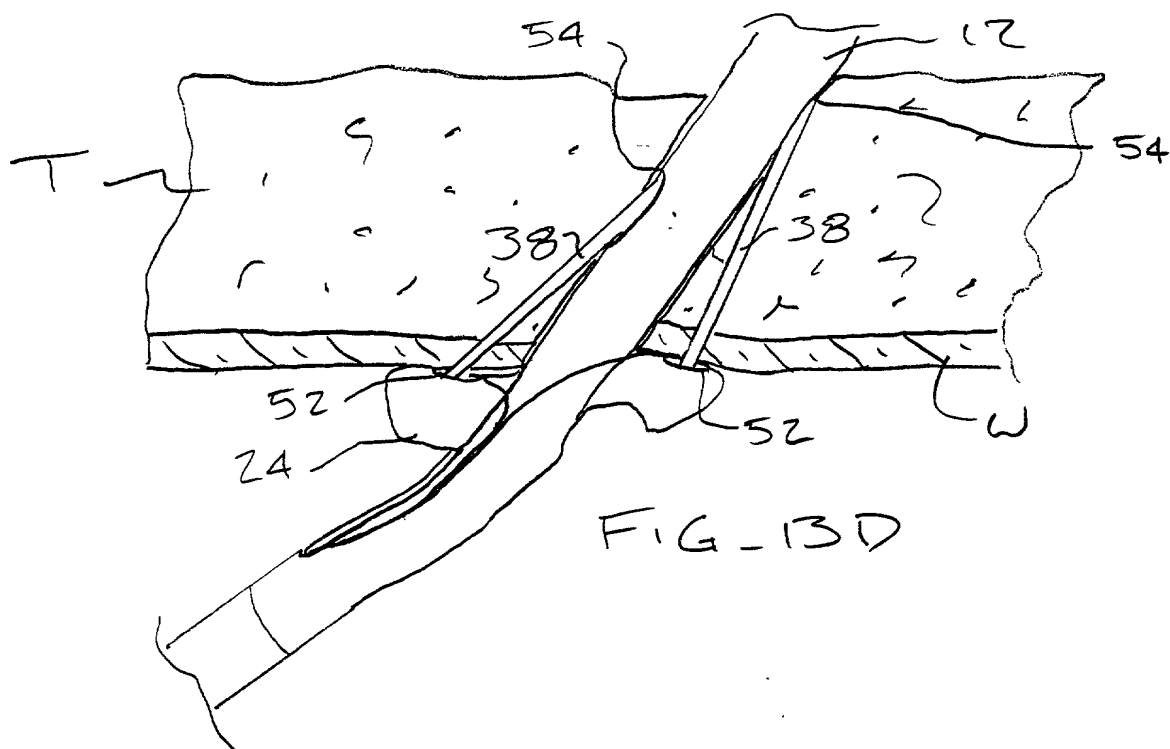


FIG-13D

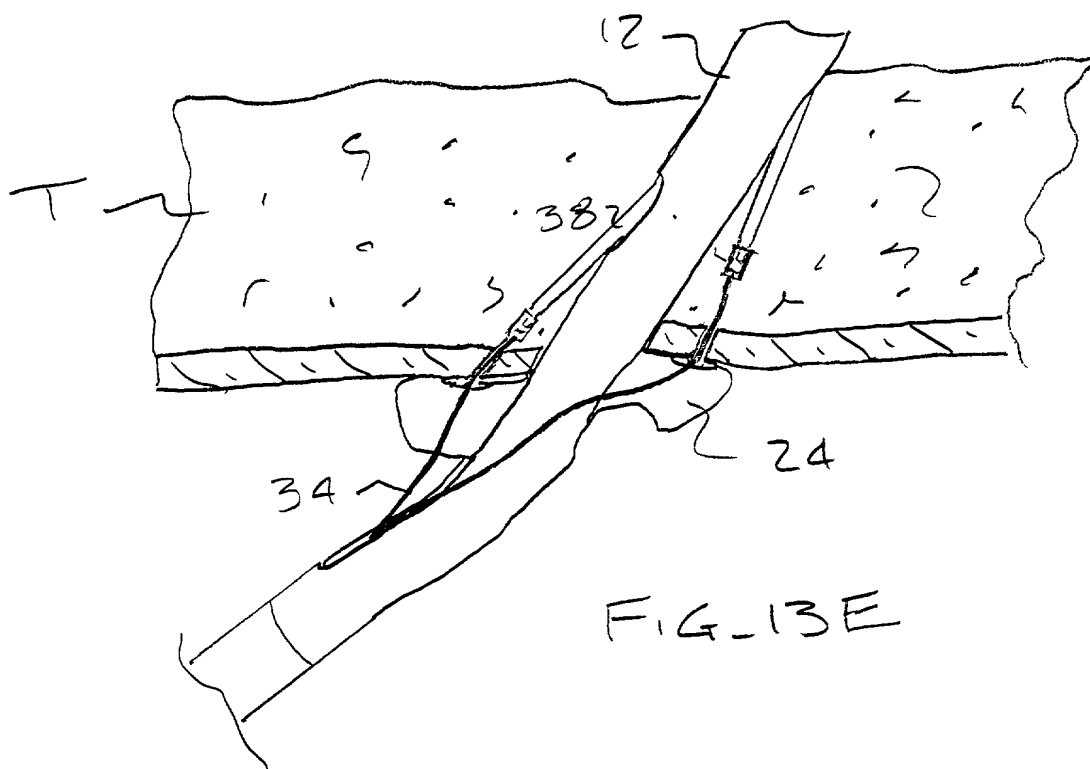


FIG. 13E

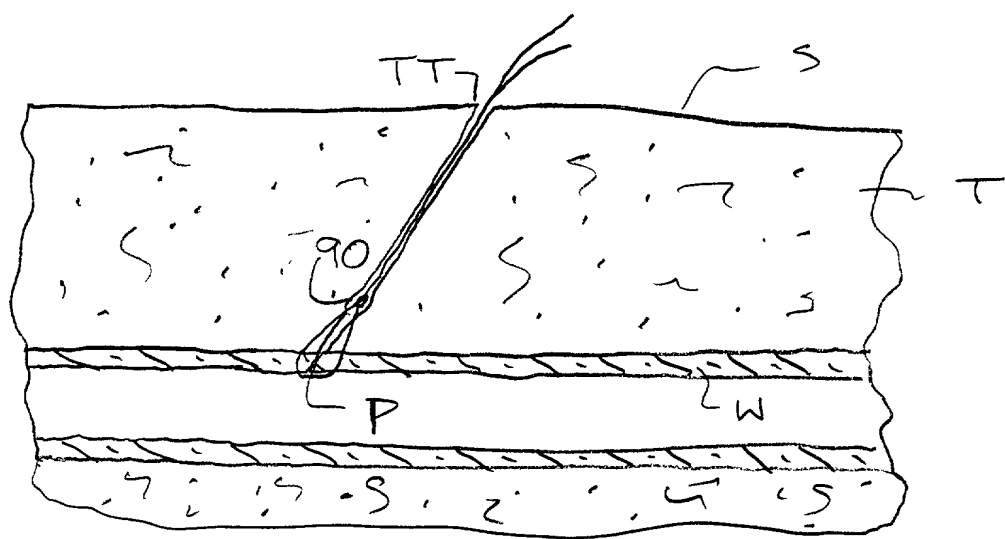
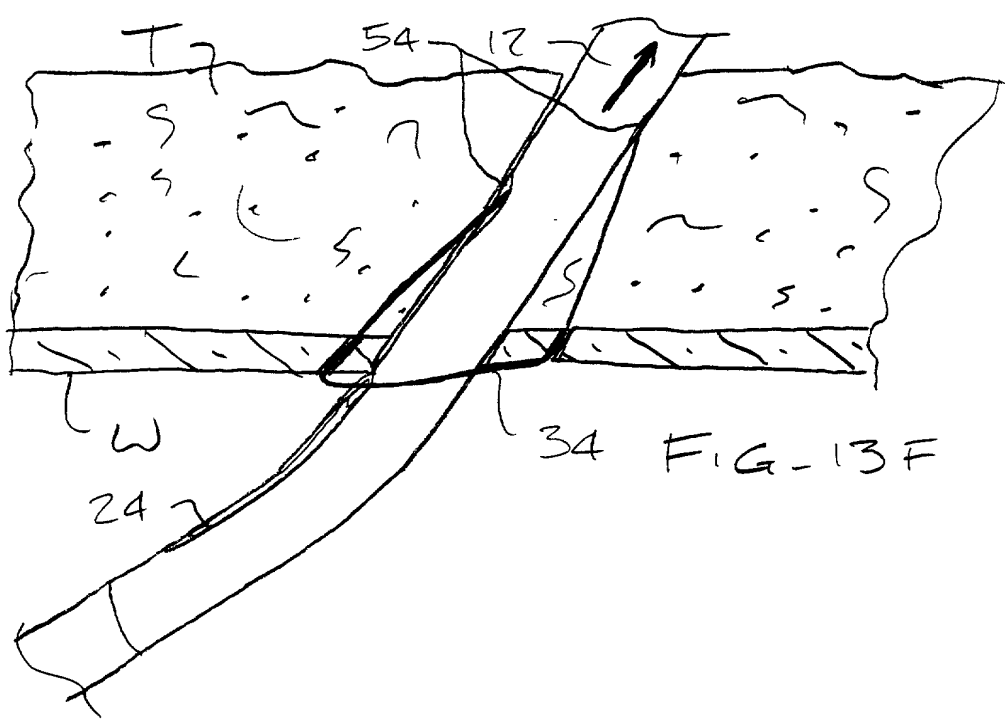


FIG-13G

**DECLARATION**

As a below named inventor, I declare that:

My residence, post office address and citizenship are as stated below next to my name; I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural inventors are named below) of the subject matter which is claimed and for which a patent is sought on the invention entitled: **ARTICULATING SUTURING DEVICE AND METHOD** the specification of which   X   is attached hereto or \_\_\_\_\_ was filed on \_\_\_\_\_ as Application No. \_\_\_\_\_ and was amended on \_\_\_\_\_ (if applicable).

I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above. I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, Section 1.56. I claim foreign priority benefits under Title 35, United States Code, Section 119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed.

**Prior Foreign Application(s)**

Country	Application No.	Date of Filing	Priority Claimed Under 35 USC 119

I hereby claim the benefit under Title 35, United States Code § 119(e) of any United States provisional application(s) listed below:

Application No.	Filing Date

I claim the benefit under Title 35, United States Code, Section 120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, Section 112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, Section 1.56 which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

Application No.	Date of Filing	Status

Full Name of Inventor 1:	Last Name: <b>MODESITT</b>	First Name: <b>D.</b>	Middle Name or Initial: <b>BRUCE</b>	
Residence & Citizenship:	City: <b>San Carlos</b>	State/Foreign Country: <b>California</b>	Country of Citizenship: <b>U.S.</b>	
Post Office Address:	Post Office Address: <b>120 Wingate Avenue</b>	City: <b>San Carlos</b>	State/Country: <b>California</b>	Postal Code: <b>94070</b>
Full Name of Inventor 2:	Last Name: <b>ZUNG</b>	First Name: <b>MICHAEL</b>	Middle Name or Initial:	
Residence & Citizenship:	City: <b>San Jose</b>	State/Foreign Country: <b>California</b>	Country of Citizenship: <b>U.S.</b>	
Post Office Address:	Post Office Address: <b>5791 Chambertin Drive</b>	City: <b>San Jose</b>	State/Country: <b>California</b>	Postal Code: <b>95118</b>
Full Name of Inventor 3:	Last Name: <b>BARRETT</b>	First Name: <b>MICHAEL</b>	Middle Name or Initial:	
Residence & Citizenship:	City: <b>Campbell</b>	State/Foreign Country: <b>California</b>	Country of Citizenship: <b>U.S.</b>	
Post Office Address:	Post Office Address: <b>677 Kenneth Avenue</b>	City: <b>Campbell</b>	State/Country: <b>California</b>	Postal Code: <b>95008</b>
Full Name of Inventor 4:	Last Name: <b>ANDREAS</b>	First Name: <b>BERNARD</b>	Middle Name or Initial: <b>H.</b>	
Residence & Citizenship:	City: <b>Fremont</b>	State/Foreign Country: <b>California</b>	Country of Citizenship: <b>U.S.</b>	
Post Office Address:	Post Office Address: <b>36812 Second Street</b>	City: <b>Fremont</b>	State/Country: <b>California</b>	Postal Code: <b>94536</b>
Full Name of Inventor 5:	Last Name: <b>ISELL</b>	First Name: <b>LEWIS</b>	Middle Name or Initial:	
Residence & Citizenship:	City: <b>Union City</b>	State/Foreign Country: <b>California</b>	Country of Citizenship: <b>U.S.</b>	
Post Office Address:	Post Office Address: <b>34800 Hollyhock Street</b>	City: <b>Union City</b>	State/Country: <b>California</b>	Postal Code: <b>94587</b>

I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Signature of Inventor 1  <b>D. BRUCE MODESITT</b>	Signature of Inventor 2  <b>MICHAEL ZUNG</b>	Signature of Inventor 3  <b>MICHAEL BARRETT</b>
Date	Date	Date
Signature of Inventor 4  <b>BERNARD H. ANDREAS</b>		Signature of Inventor 5  <b>LEWIS ISELL</b>
Date		Date